

2021 WL 4146907

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United States District Court, D. Wyoming.

Jessica Ann FOX, as Personal Representative of the Estate of Iletha

Ann Hamang, Deceased, and [Stageline Express, Inc.](#), Plaintiffs,

v.

Vladimir MAKARCHUK, EEZ Trucking, Inc., and United Shippers Associates, Inc., Defendants.

[EEZ Trucking, Inc.](#), Counterclaim Plaintiff,

v.

Stageline Express, Inc., Counterclaim Defendant.

[EEZ Trucking, Inc.](#), Third-Party Plaintiff,

v.

Carl Hector, Third-Party Defendant.

Case No. 19-CV-207-J

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Signed 05/11/2021

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ORDER DENYING PLAINTIFF'S MOTION TO STRIKE [65]

[Kelly H. Rankin](#), United States Magistrate Judge

*1 This Matter comes before the Court on *Plaintiff Jessica Fox's Motion to Strike/Exclude, in Part, Defendants' Expert, Bruce Y. Newton, M.D.* (ECF No. 65). Plaintiff moves to strike the portion of Defendants' expert witness testimony that assigns percentage allocations to the cause of Ms. Hamang's injuries. Plaintiff argues Dr. Newton's conclusion is unreliable because it does not have a scientific basis. In making a reliability determination, the Court must focus "solely on the principles and methodology, not on the conclusions that they generate." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993). The

Court finds Dr. Newton's methodology of reviewing Ms. Hamang's medical records and using his experience, knowledge, and training to form an opinion is reliable.

BACKGROUND

This case arises from an accident between two semi-trucks on Interstate 80 in Evanston, Wyoming. Defendant Vladimir Makarchuk was driving a vehicle owned by Defendant EEZ Trucking, Inc. Ms. Hamang was a passenger in Third-Party Defendant Carl Hector's truck, owned by Plaintiff and Counter-Claim Defendant Stageline Express. At the time of the accident, Ms. Hamang was sleeping in the vehicle's sleeper berth. When the two vehicles collided, Ms. Hamang was ejected from the sleeper. She suffered severe injuries including a left proximal femur fracture, which required surgery.

Paramedics first transported Ms. Hamang to Evanston Regional Hospital in Evanston, Wyoming for surgery on her femur. Afterwards, she was transferred to Northern Utah Rehabilitation Hospital. There, she suffered from [acute bowel obstruction](#) that developed post-surgery. She was then transferred to Ogden Regional Medical Center for treatment. Next, she was transferred to St. Mark's Hospital in Salt Lake City, Utah where she was diagnosed with [ascending aortic aneurysm](#) with dissection. This diagnosis required an additional surgery.

On October 11, 2018, Ms. Hamang underwent the [ascending aortic aneurysm](#) surgery and was admitted to the ICU. There, she developed [acute renal failure](#). She ultimately recovered and was discharged from St. Mark's Acute Rehabilitation Center on November 6, 2018. Ms. Hamang died for unknown causes on May 13, 2019. This action is therefore pursued as a Survival Action under [Wyo. Stat. § 1-4-101](#) through Personal Representative of the Estate Jessica Ann Fox.

Defendants submitted their expert report of Bruce Y. Newton, M.D. on November 2, 2020. (ECF No 65, at Ex. 1). Plaintiff moves to strike portions of Dr. Newton's report that apportions percentages of the treatment Ms. Hamang received between injuries caused by the accident and pre-existing conditions that were exacerbated by the accident. Plaintiff argues his allocation of percentage is unreliable because it is not based in science, subject to peer review or publication, has no known rate of error, cannot be tested, and is not generally accepted within the relevant community. Plaintiff asserts Dr. Newton "simply picked a number out of a hat and conceded that he did so with no rational, let alone scientific, basis." (ECF No. 65 at 8). Plaintiff concedes Dr. Newton's testimony concerning Ms. Hamang's underlying pathologies may be relevant but argue there is too big an analytical gap for Dr. Newton to allocate percentages.

*2 In response, Defendants assert Dr. Newton utilized reliable methodology and analyzed sufficient facts and data in the formulation of his opinions.¹ Defendants argue Dr. Newton's opinion rests on good grounds because he has extensive knowledge, skill, training and expertise in the medical field, including with apportionment and allocation of injuries, in situations where pre-existing issues are a concern. (ECF No. 73). Further, Defendants assert the proper place for Plaintiff to criticize Dr. Newton's opinions is during cross examination. (ECF No. 73, at 3).

RELEVANT LAW

The Court begins by noting district courts have broad discretion in determining the admissibility of expert testimony. [Taylor v. Copper Tire & Rubber Co.](#), 130 F.3d 1395, 1397 (10th Cir. 1997). In utilizing this discretion, the Court will first look to the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Wyoming regarding expert witness designations. Pursuant to the federal and local rules, opposing parties are entitled to a detailed disclosure of the information that adversarial experts are relying upon in formulating their expert opinions. [Fed. R. Civ. P. 26\(a\)\(2\)](#); U.S.D.C.L.R. 26.1 (e); [Smith v. Ford Motor Co.](#), 626 F.2d 784, 795–96 (10th Cir. 1980).

The proponent of the expert testimony bears the burden of proving the foundational requirements of Rule 702 by a preponderance of the evidence. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). Rule 702 of the Federal Rules of Evidence provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Each expert's opinions are subject to the same standards of reliability that govern the opinions of strictly scientific experts retained for the purposes of litigation. See *Kumho Tire Co., Ltd.*, 526 U.S. at 151 (holding *Daubert* applies even when an expert's opinion relies on skill or experience-based observation). Rule 702 and *Daubert* require courts act as gatekeepers by ensuring all expert testimony, whether scientific, technical, or any other specialized knowledge, is both reliable and relevant. *Id.* at 152-53. In order to make the requisite findings, the Court must first determine whether the expert is qualified by knowledge, skill, experience, training, or education to render an opinion. See *id.* Second, the Court must determine whether the expert's opinions are sufficiently reliable. See *id.*; Fed. R. Evid. 702; *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969 (10th Cir. 2001). Finally, the court must determine whether the proposed expert testimony will assist the trier of fact. Fed. R. Evid. 702.

To offer expert testimony, an expert's qualifications may be based on “knowledge, skill, experience, training, or education[.]” *Id.* It is not paramount that witnesses satisfy all of these qualifications to testify as an expert because a witness is qualified to testify as an expert so long as the witness' overall qualifications provide expertise relevant to the opinions offered. *Id.* (advisory committee's notes to 2000 amendment); *United States v. Crabbe*, 556 F. Supp. 2d 1217, 1221 (D. Colo. 2008) (citing *United States v. Dysart*, 705 F.2d 1247, 1252 (10th Cir. 1983)). As a result, Rule 702 is to be liberally construed in that it “does not impose an ‘overly rigorous’ requirement of expertise, recognizing that specialized knowledge may be acquired through a broad range of experience, skills or training.” *Squires v. Goodwin*, 829 F. Supp. 2d 1041, 1048 (D. Colo. 2011) (citing *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995)). In short, a person is qualified to offer expert testimony so long as they possess such skill, experience, or knowledge so that the opinion rests on a substantial foundation that will aid the trier of fact. *Squires*, 829 F. Supp. 2d at 1048 (citing *LifeWise Master Funding v. Telebank*, 374 F.3d 917, 928 (10th Cir. 2004)).

*3 Regarding methodology and procedures under *Daubert*, a court is to find an expert opinion reliable under Rule 702 if the opinion is based on “good grounds.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994). Meaning that, if the opinions are based on methods and procedures of science, they can be admissible regardless of whether the court thinks the opinions are correct. *Id.* The court's focus “must be solely on principles and methodology, not on the conclusions that they generate.” *Id.* at 744 (quoting *Daubert*, 509 U.S. at 595).

Rule 702 requires the evidence or testimony presented assist “the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702. “In assessing whether testimony will assist the trier of fact, district courts consider several factors, including whether the testimony is within the juror's common knowledge and experience, and whether it will usurp the juror's role of evaluating a witness's credibility.” *United States v. Garcia*, 635 F.3d 472, 476–77 (10th Cir. 2011) (internal quotations omitted). Any questions about whether an expert's testimony will be helpful should be resolved in favor of admissibility unless there are factors requiring exclusion, such as timing or surprise, as the jury is intelligent enough to decipher the helpful from the unhelpful in its deliberations. *United States v. Gutierrez de Lopez*, 761 F.3d 1123, 1136 (10th Cir. 2014). Additionally, Rule 702's “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Daubert*, 509 U.S. at 595. To meet the requisite connection, expert opinions must provide the underlying facts and basis of the

expert's opinions. "Opinions are valueless as evidence without exploration of the underlying facts and rationale showing the path from the facts to the opinion." *United States v. R.J. Reynolds Tobacco Co.*, 416 F. Supp. 316, 325 (D. N.J. 1976).

Expert witnesses are also prohibited from invading the purposes of a jury. An expert witness may not "state legal conclusions drawn by applying the law to the facts." *Okland Oil Co. v. Conoco Inc.*, 144 F.3d 1308, 1328 (10th Cir. 1998). Moreover, an expert witness may not instruct the jury on applicable law. *Specht v. Jensen*, 853 F.2d 805, 807–08 (10th Cir. 1988). However, "expert witnesses in civil cases may testify in the form of an opinion or inference as to ultimate issues to be decided by the trier of fact if the testimony is not otherwise objectionable." *Okland Oil Co.*, 144 F.3d at 1328 (citing Fed. R. Evid. 702; *Williams Natural Gas Co. v. Perkins*, 952 P.2d 483, 490 (Okla. 1997); *Gabus v. Harvey*, 678 P.2d 253, 255–56 (Okla. 1984)).

RULING OF THE COURT

Plaintiff concedes Dr. Newton's testimony is relevant and does not argue Dr. Newton is unqualified. Rather, Plaintiff argues a portion of Dr. Newton's testimony is unreliable.

Dr. Newton's Methodology is Reliable

Questions of reliability may concern the expert's data, methodology, or his application of the method to the data. *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009). In making a reliability determination, the Court must focus "solely on the principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. The testimony Plaintiff moves to strike is:

In summary, it is my opinion that there is a likelihood that the motor vehicle accident triggered worsening of a preexisting thoracic ascending aortic pathology, but in the absence of the preexisting condition, it is highly unlikely that the motor vehicle accident would have caused a need for this surgery. I would therefore opine that, although the motor vehicle accident may have hastened the need for surgery, it is likely that had she survived very long, this surgery would have been inevitable. I would therefore assign 65 percent responsibility to her preexisting condition and a 35 percent responsibility to the motor vehicle accident.

*4 (ECF No. 65, at Ex. 1). Plaintiff's argue Dr. Newton's percentage allocation has no basis in science or fact, has not been subject to peer review or publication, has no known rate of error, cannot be tested, and is generally not accepted within the relevant community. They also argue Dr. Newton has never published or lectured on his percentage allocation methodology. While the factors Plaintiff lists are certainly relevant to Rule 702's non-exhaustive list of reliability considerations, the trial court has broad discretion to consider a variety of factors. *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1205 (10th Cir. 2002); *Kumho Tire CO.*, 525 U.S. at 141–42 ("[T]he law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.") (emphasis in original; internal quotations omitted).

For example, a district court's reliability determination might consider the type of expert opinion offered. See *J&R Well Serv., LLC v. Horizontal Rentals, Inc.*, No. 11-cv-206-F, 2011 WL 13112086, at *1 (D. Wyo. Nov. 3, 2011). If purely scientific testimony is at issue, the methodology can be tested against its falsifiability, refutability, or testability. *Daubert*, 509 U.S. at 593. If, on the other hand, purely experiential testimony is at issue, the methodology cannot necessarily be tested under such a scientific lens. See *J&R Well. Serv.*, 2011 WL 13112086, at *1. Thus, the issue of whether experiential expert testimony is reliable is "somewhat more opaque." *Id.* Even if experiential expert testimony does not rely on the scientific method, this does "not lead to a conclusion that experience alone—or experience in conjunction with other knowledge, skill, training or education

—may not provide a sufficient foundation for expert testimony.” *U.S. v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (internal quotations omitted).

In this case, Dr. Newton offers a combination of scientific testimony and experiential expert testimony. Accordingly, Dr. Newton's qualifications, though not entirely disputed by Plaintiff, are important considerations for the purposes of reliability. Dr. Newton is a board-certified medical doctor in physical medicine and rehabilitation. Dr. Newton has experience addressing the question of apportionment or allocation of injuries in civil cases and in workers compensation matters. Dr. Newton contributed to the industrial or labor commission's guidelines for apportionment under a worker's compensation system and he stated he works “frequently in devising systems for determination of fair apportionment.” (ECF No. 73, at Ex. C). Dr. Newton explained there are “rational means” to determine apportionment, and specifically referenced those systems. The Court finds Dr. Newton's experience sufficiently supports that Dr. Newton can reliably apply his knowledge to the medical data to form an opinion.

Plaintiff argues further Dr. Newton's opinions create too big an analytical gap from the data he relied on and his percentages were simply “pulled from a hat.” Plaintiff asserts she cannot cross examine Dr. Newton on his opinion because it is based solely “on his say-so.” The Court disagrees. Dr. Newton's report demonstrates his methodology consisted of reviewing medical records to form his conclusions and there is a sufficient connection between the data and his opinion. First, Dr. Newton relies on medical records, medical scans, imaging, and medical documents from the collision and one year prior. He reviewed Ms. Hamang's medical records from Bergen Mercy Medical Center, St. Mark's Hospital, Ogden Regional Center, Northern Utah Rehabilitation, Fremont Health Clinic, Uintah County Ambulance, Evanston Regional Hospital, and other locations. Dr. Newton's report includes over five paragraphs of facts and data he analyzed before ultimately forming his percentage apportionment conclusion. (ECF No. 73, at Ex. D). Plaintiff has offered no argument for why the medical records and data Dr. Newton used are unreliable or wouldn't be relied on by experts in the same field. Further, as explained above, Dr. Newton's knowledge and experience is sufficient to find his analysis and conclusion reliable.

*5 To conclude, Dr. Newton's experience in conjunction with other knowledge, skill, training, and education provides a sufficient foundation for him to reliably apply the facts and data and reach an opinion on the percentage apportionment causes of Ms. Hamang's injuries. Further, Dr. Newton's report identifies sufficient facts and data to support his opinion.

CONCLUSION

Here, it is immaterial that Dr. Newton's *opinions* in this case are not published, have not been peer reviewed, or generally accepted within the scientific community. Defendants are not required to demonstrate Dr. Newton “is undisputedly correct.” *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1234 (10th Cir. 2005). The proper consideration is whether the *methodology* he used to arrive at his opinion satisfies the standards contemplated in *Daubert*. Accordingly, Dr. Newton's testimony is admissible under *Daubert* and Rule 702, and Plaintiff's Motion must be denied.

The Court is mindful of the fact that reliable methods may not always produce reliable conclusions. But *Daubert* only requires courts to consider the former. It is best left for the jury to determine how much weight to give Dr. Newton's conclusions, and vigorous cross examination is the best avenue for presenting Plaintiff's concerns with Dr. Newton's opinions. *See, e.g., Watson v. United States*, 485 F.3d 110, 1110 (10th Cir. 2007).

THEREFORE, Plaintiff's Motion to Strike is DENIED [65].

All Citations

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Footnotes

- 1 Defendants also argue Plaintiff did not properly confer prior to filing their motion The Court finds Plaintiff failed to properly confer but will regardless address the Motions on the merits.

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2009 WL 1208014

United States District Court, E.D. Kentucky,
Central Division, at Frankfort.

UNITED STATES of America, Plaintiff,

v.

Leonard LAWSON, Charles William Nighbert and Brian Russell Billings, Defendants.

Criminal Action No. 3:08–21–DCR.

|

May 1, 2009.

West KeySummary

1 **Criminal Law** Knowledge, Experience, and Skill

The government's witness was properly qualified to be admitted as an expert at defendant's trial for bribery, witness tampering, and obstruction of justice. The proffered expert possessed the experience, training and education to qualify as an expert. The expert's testimony was probative of whether the defendant had the mechanisms in place to commit the acts with which he was charged. Further, the proffered testimony would assist the jury in understanding facts at issue because it distilled the relevant portions of business financial and legal documents. [Fed.Rules Evid.Rule 702, 28 U.S.C.A.](#)

[5 Cases that cite this headnote](#)

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ORDER

[DANNY C. REEVES](#), District Judge.

*1 This matter is pending for consideration of the United States Magistrate Judge's Report and Recommendation concerning Defendant Lawson's motion to exclude the government's proffered expert witness. [Record Nos. 128 and 330] The Magistrate Judge has recommended that the Defendant's motion be denied and that his request for alternative relief be denied.

Because the Court agrees with the analysis contained in the Report and Recommendation, and because the Defendant has not objected to the Report and Recommendation within the time permitted, the recommendation will be adopted in full. Accordingly, it is hereby

ORDERED as follows:

1. The Report and Recommendation of United States Magistrate Judge James B. Todd [Record No. 330] is **ADOPTED** and **INCORPORATED** herein by reference.
2. Defendant Lawson's motion to exclude *in limine* the government's proffered expert witness [Record No. 128] is **DENIED**. Likewise, the Defendant's request for alternative relief consisting of a perfected 16(a)(1)(G) disclosure and a witness qualification hearing is **DENIED**.

MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION

JAMES B. TODD, United States Magistrate Judge.

I. INTRODUCTION

On December 3, 2008, defendant Leonard Lawson filed a motion to exclude *in limine* the government's proffered expert witness pursuant to [Federal Rules of Evidence 702](#) and [403](#), as well as [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#). [DE # 128]. On December 17, 2008, the United States filed a response to the motion. [DE # 173]. On January 6, 2009 the defendant filed a reply to respondent's response. [DE # 201]. Thus, this matter is ripe for review.

In accordance with local practice, this matter was referred to the undersigned Magistrate Judge for consideration pursuant to [28 U.S.C. § 636\(b\)](#).

II. DISCUSSION

A. Factual and Procedural History

On September 3, 2008, a federal Grand Jury returned an eight-count indictment against movant and his co-defendants, charging movant with bribery, witness tampering, and obstruction of justice. Movant pled not guilty to these charges. Trial is scheduled to begin on June 23, 2009.

On September 3, 2008 defendant Lawson's counsel requested by letter that the United States disclose any items that it intends to use under [Federal Rules of Evidence 702](#), [703](#), [705](#), or [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#). The letter also requested that the United States disclose information called for under [Fed.R.Crim. Proc. 16\(a\)\(1\)](#) generally, and [FRE 801\(d\)\(2\)\(E\)](#) or [FRE 404\(b\)](#) in particular.

On November 3, 2008 the government responded to defendant's letter with notification that the United States intends to call a witness with "specialized knowledge" to testify. The letter included the conclusions to which the witness would testify, the reasons for the witness's conclusions, and the witness's résumé.

On November 6, 2008 defendant Lawson's counsel replied to the government stating that the government's letter of November 3, 2008 did not include a summary of the bases and reasons upon which the expert witness relies, one of [Rule 16\(a\)\(1\)\(G\)](#)'s requirements.

*2 On December 3, 2008 defendant Lawson filed his *First Motion to Exclude in Limine Government's Expert Witness*.

B. Movant's claims

In support of the motion to exclude the government's expert witness, movant asserts that: (1) the government's proffered witness lacks the qualifications to be admitted as an expert under [Fed. Rule Evid. 702](#); (2) expert testimony will not assist and is not necessary for the jury to understand the movant's interest in the corporation whose documents the expert would analyze and thus fails the "need" element of [Fed. Rule Evid. 702](#); (3) the proffered testimony's relevance is for the jury to decide; (4) the expert's proffered opinion invades the province of the jury because it introduces state of mind testimony; (5) the expert's testimony would have a prejudicial effect that outweighs its probative value under [Fed. Rule Evid. 403](#); and (6) the government provided insufficient notice under [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#) because the notice did not include the "bases and reasons" for the proffered expert's opinion testimony.

The United States filed a *Response to Motion to Exclude Expert Testimony* which stated the following: (1) there is a need for an expert witness because some of the evidentiary documents are not within the knowledge and understanding of many jurors; (2) the government might not call the expert, but must be prepared to impeach witnesses who testify at odds with the evidentiary documents; (3) the proffered witness is qualified to be an expert by her experience, education, and training because of her extensive auditing experience; and (4) the government will not ask the expert the thoughts of others.

The movant replied with a *Reply Memorandum in Support of First Motion to Exclude in Limine Government's Expert Witness* and stated: (1) expert testimony will not assist the jury because the evidentiary documents are not complex enough to merit expert assistance; (2) the government's need for someone to provide their desired testimony is not a proper basis for the admission of expert testimony; (3) the proposed use of expert testimony is an attempt to introduce state of mind testimony; and (4) the government provided insufficient notice under [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#) because "bases and reasons" for the proffered testimony were not provided.

C. Applicable Law

The movant challenges the government's proffered witness in two areas: the substantive rules regarding expert qualification under the Federal Rules of Evidence and related caselaw, as well as the procedural requirements of the Federal Rules of Criminal Procedure.

In considering the movant's claims, the court must consider [Federal Rules of Evidence 104\(a\)](#), 401, and 402. It is the court's duty to independently analyze the available information regarding the qualification of a witness. [Fed. Rule Evid. 104\(a\)](#). All relevant evidence is admissible. [Fed. Rule Evid. 402](#).

***3 Expert testimony admissibility.** The admissibility of expert testimony is governed by [Federal Rules of Evidence 104\(a\)](#), 401, and 702. There is also governing caselaw to consider from *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

[FRE 104\(a\)](#) states: "Preliminary questions concerning the qualification of a person to be a witness ... shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges."

[FRE 401](#) states that admissible evidence is that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable that it would be without the evidence."

[FRE 702](#) states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case ." This rule presents six elements to be satisfied: (I) the need to help the jury to understand evidence or to determine

a fact in issue, (ii) the need for scientific, technical, or other specialized knowledge regarding evidence or a fact in issue, (iii) presented by a witness qualified as an expert by knowledge, skill, experience, training or education, (iv) the witness's testimony is based on sufficient facts or data, (v) the witness employs reliable principles and methods in reaching his or her conclusions, and (vi) the witness reliably applied the principles and methods to the facts.

FRE 702 was amended in 2000, in light of the *Daubert* and *Kumho Tire* opinions from the Supreme Court of the United States. *Daubert* held that Rules 104(a) and 702 set gatekeeping requirements for trial judges, a function that requires the court to determine the reliability of the scientific, technical or specialized knowledge undergirding the proffered expert's testimony. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–93, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The Court identified the following factors as helpful in performing a reliability analysis: (I) whether a particular theory or technique has been tested; (ii) “whether the theory or technique has been subjected to peer review and publication,” (iii) the known or potential rate of error for the theory or technique, (iv) the existence of standards in applying the theory or technique, and (v) whether the theory or technique enjoys “general acceptance” within the scientific community. *Daubert*, 509 U.S. at 593–94. The particulars of the *Daubert* case applied to scientific testimony regarding pharmaceutical research and, as such, the analytical factors suggested by the court focus on scientific testimony and information. *Daubert* does not speak directly to “technical” or “specialized knowledge” testimony that is also within the purview of FRE 702.

*4 *Kumho Tire* addressed “technical” and “specialized knowledge” in light of *Daubert*. It held that the *Daubert* reliability analysis applies to all expert testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). The objective of examining the reliability of expert testimony is to ensure that every expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152. The court may enquire into the methodology used to reach the conclusions presented in the testimony and apply the *Daubert* factors to the extent that they are helpful. *Kumho Tire*, 526 U.S. at 151. The trial judge has broad latitude in testing an expert's reliability, subject to an abuse of discretion standard. *Kumho Tire*, 526 U.S. at 152.

Auditors are an example of “specialized knowledge” expert. The foundations for their expert testimony do not fall into “scientific” or “technical” categories. Auditors are methodical and have standards for their profession, but they do not “test” their methodologies in the manner than laboratory scientists do, nor do they work with “technical” specifications as engineers or computer scientists do. The nature of their work makes application of the *Daubert* factors awkward.

Despite such analytical awkwardness, the accrual of specialized knowledge through experience is sufficient to create expertise. *Berry v. City of Detroit*, 25 F.3d 1342, 1349–50 (6th Cir.1994). So long as the testimony content is relevant and the method by which the specialized testimony developed is reliable, a specialized knowledge witness is an expert witness. *Id.* at 1351. Reliability in specialized knowledge testimony is indicated by testing the theory or technique and applying any other relevant *Daubert* factors. *Id.* at 1350. Courts err when they permit witnesses with specialized knowledge to testify as lay witnesses. When a witness presents information that is outside the working knowledge of an average lay person, then the need for an expert exists. *U.S. v. White*, 492 F.3d 380, 403 (6th Cir.2007).

Audit experts rely upon their practical experiences that are relevant to a matter at issue. Their credentials are not their only relevant background. Auditors can be experts even when they are not CPAs. *U.S. v. Winkle*, 477 F.3d 407, 416 (6th Cir.2007). An auditor with many years of practical experience in performing audit work relevant to the issue being litigated qualifies to be a witness so long as the methods employed are reliable. *Id.* at 415–16.

In the Eastern District of Kentucky, a range of relevant factors have been identified regarding the qualification of specialized knowledge experts. Relevant factors include the proffered expert's knowledge of an industry and knowledge of an industry's common practices, in addition to the expert's demonstrated relevant experience, training, and education. *Oaks v. Wiley Sanders Truck Lines, Inc.*, 2008 WL 4180267, at *3 (E.D.Ky.2008). Scientific tests or the application of mathematical formulas are not a necessary foundation for expert testimony that is technical or based on specialized knowledge. *In re Air Crash at Lexington, Kentucky*, 2008 WL 2954973, at *3 (E.D.Ky.2008).

***5 Expert testimony disclosures in federal criminal trials.** The government's required disclosures regarding expert testimony when prosecuting a federal crime is governed by [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#), which states: "At the defendant's request, the government must give to the defendant a written summary of any testimony that the government intends to use under [Rules 702, 703, or 705 of the Federal Rules of Evidence](#) during its case-in-chief at trial.... The summary provided under this subparagraph must describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications."

E. Analysis

1. Qualifications of the government's proffered witness under [Fed. Rule Evid. 702](#).

Movant contends that the proffered witness isn't properly qualified because she lacks the knowledge, training, and experience necessary to render opinions on "corporate and financial implications of documents related to UMG; conclusions regarding the nature and extent of Lawson's ownership interests in UMG; and/or attempts to conceal Lawson's ownership interests in UMG." *Defendant's Memo in Support of First Motion*, at 4. Additionally, defendant claims that the proffered witness lacks knowledge, training, and experience because she is not a Certified Public Accountant, "she has not focused upon or specialized in the area of partnership structures and/or partnership distributions," and her audit work does not "provide a background sufficient ... to testify regarding the implications of corporate and financial documents." *Defendant's Memo in Support of First Motion*, at 5. Defendant also argues that the proffered expert's experience "performing audits under the International Fuel Tax Agreement and auditing trucking companies for compliance with the State Weight Distance Fuel Tax provides no relevant knowledge base whatsoever for her purported testimony in this matter." *Defendant's Memo in Support of First Motion*, at 5. The defendant goes on to state that the government did not provide any information regarding the proffered expert's basis for her conclusions and opinions, and as such, makes it impossible to determine whether the proposed testimony is reliable and relevant, prerequisites to qualifying an expert witness. *Defendant's Memo in Support of First Motion*, at 5–6.

It is an auditor's job to analyze the implications of corporate and financial documents. The proffered witness has ten years of experience auditing financial documents, keeps up with continuing professional education, and has an appropriate educational background for auditing. *Defendant's First Motion to Exclude*, Attachment B. It is not necessary to be a CPA in order to be an audit expert. *Winkle*, 477 F.3d at 416. [Rule 702](#) only requires expertise acquired by "knowledge, skill, experience, training or education." The proffered expert's résumé demonstrates education, training, and experience. It is not necessary to specialize in partnership structures or distributions to understand what business documents regarding partnerships intend to effectuate. The scope of inquiry concerns the consequences of business structures and distributions; the fact that these are partnership structures and distributions is not relevant.

***6** The International Fuel Tax Agreement audit experience is from more than ten years ago according to the proffered expert's résumé. *Defendant's First Motion to Exclude*, Attachment B. Since 1999, the proffered expert has worked on auditing financial documents. Financial and business documents are the foundation for the expert's analysis and their contents are relevant to the ultimate matters at hand.

The basis for the proffered expert's conclusions and opinions includes the expert's knowledge and experience as documented in her résumé as well as the business documents disclosed with the government's *Response to the Motion to Exclude*. This makes it possible to determine that the testimony is relevant (because it is probative of the allegations against defendant) and reliable (because professional auditors examine documents for evidence of fraud based on professional audit standards). Although the government did not provide this information with its letter of November 3, 2008, the "bases" information is now in defendant's hands because the documents were appended to the government's *Response*.

Defendant goes on to argue that even if the witness is "properly qualified," expert testimony is not necessary for and will not assist the jury in understanding defendant's interest in the corporation whose documents the expert would analyze. Defendant alleges that the conclusions disclosed by the government do not require specialized knowledge to understand, that

the government has the burden of demonstrating that specialized knowledge is helpful to the jury, and that they have not done so. *Defendant's Memo in Support of First Motion*, at 10. Defendant claims that the government has not given a reason why the jury could not review and understand the documents on their own and that it is the government's burden to demonstrate “by a preponderance of the evidence that the proposed testimony is justified under *Daubert*.” *Defendant's Memo in Support of First Motion* at 10, citing *Oaks v. Wiley Sanders*, 2008 WL 418027, at *3 (E.D.Ky.2008)(citing *Daubert*, 409 U.S. at 593). Defendant also states that the government's need for expert testimony is based on its desire to impeach witnesses and that the government's need for “someone to provide the desired testimony is simply not a proper basis for invoking expert witness testimony.” *Defendant's Reply Memorandum*, at 3–4 (emphasis in original).

The Court has the duty of weighing the admissibility of evidence and the need for expert testimony under [Federal Rules of Evidence 104\(a\)](#), 401 and 702. The conclusions disclosed by the United States are supported by evidence consisting of business documents and records. This evidence is lengthy and complex. It will help the jury to understand the documents if someone with specialized knowledge explains the relevant portions of the documents.

It is also the Court's duty under [FRE 104\(a\)](#) and 702 to act as a gatekeeper and independently weigh the need for and validity of expert testimony. *Daubert*, 509 U.S. at 592–93. The government has demonstrated a need for the specialized knowledge by identifying that “some of the documents are not within the purview of knowledge and understanding of many jurors.” *Government's Response to Motion*, at 3. This does not mean that the jury cannot review the documents on their own, but it does sufficiently raise the issue of whether the jurors could analyze the documents on their own based on their lack of working knowledge regarding business financial and legal documents. *White*, 492 F.3d at 403. There is no preponderance of the evidence standard under *Daubert* necessary to justify the proposed testimony. The caselaw to which defendant cites does not support that proposition and the citation to *Daubert* referred to in defendant's memorandum does not exist in *Oaks v. Wiley Sanders*. The government has provided sufficient information to satisfy [FRE 702](#) and those are the only requirements that the government need meet regarding need for and validity of expert testimony.

*7 Next, defendant argues that testimony regarding defendant's “apparent attempts to conceal” ownership of the corporation wouldn't assist the jury and so isn't appropriate subject matter for expert testimony. *Defendant's First Motion to Exclude*, at 2. Defendant argues that the proffered expert cannot testify that the defendant's ownership interest in UMG constitutes apparent attempts to conceal his identity from public view because “if such evidence is relevant, the decision is the jury's.” *Defendant's Memo in Support of First Motion* at 12.

It is the jury's role to weigh the evidence regarding the ultimate issues litigated. That is, it is the jury's responsibility to find the ultimate facts. It is the Court's decision under [Federal Rules of Evidence 104\(a\)](#) and 401 whether evidence is relevant and therefore admissible. The conclusion that “the defendant attempted to conceal his identity from public view” is an opinion that can be presented by an expert qualified under [FRE 702](#). The jury may then weigh the evidence in its deliberations regarding the ultimate facts.

Defendant also argues that testimony regarding Lawson's apparent attempts to conceal ownership of the corporation would invade the province of the jury and so isn't appropriate subject matter for expert testimony. “[C]onclusory statements or an opinion as to the defendant's state of mind is not proper subject matter for expert testimony because it would not be of assistance to the jury.” *Defendant's Memo in Support of First Motion*, at 13. Defendant claims that the way in which the government proposes to use the expert testimony is an attempt to introduce state of mind testimony. *Defendant's Reply Memorandum*, at 7–8. “Any proffered conclusions suggesting wrongdoing based on the nonpublic status of certain business records would be based on faulty logic and would prove nothing of relevance in this case.” *Defendant's Memo in Support of First Motion*, at 14.

The government sufficiently addressed this concern in its *Response* to the defendant's motion to exclude. The government stated that it will not seek to elicit state of mind testimony. *Government's Response to Motion*, at 5. Additionally, the trial judge will respond to any attempt to elicit state of mind testimony upon the objection of defendant's counsel. The allegation of “faulty logic” is an argument to be made to the jury. The proffered expert testimony is probative of the merits of this litigation

and admissible under [FRE 702](#); if the logic underlying the government's use of this testimony is faulty, counsel will have the opportunity to address that issue in arguments at trial.

The Magistrate Judge concludes that the movant has not established that the proffered expert lacks the knowledge, skill, or education to qualify as an expert witness. The court's review of the proffered expert's background finds that the proffered expert possesses the experience, training, and education to qualify as an expert under [FRE 702](#). The proffered expert's testimony is relevant to the issues being litigated because it is probative of whether defendant had the mechanisms in place to commit the acts with which he is charged. The proffered expert testimony will assist the jury in understanding facts at issue because it distills the relevant portions of the business financial and legal documents. The proffered expert has the education, training, and experience necessary to analyze the documents based on her educational background, accumulated years of professional experience, and ongoing training as an auditor. The factual basis for the expert's conclusions, consisting of business documents, is sufficient. The witness relies upon the auditing standards of her profession in reaching her conclusions and those standards are generally considered reliable. It appears that the witness has reliably applied auditing standards to the business documents because the conclusions disclosed in the government's November 3, 2008 letter are easily found when reviewing the business documents. The proffered expert testimony meets the requirements of [Rules 401](#) and [702](#) and is therefore admissible. Consequently, the Magistrate Judge concludes that the movant is not entitled to exclude the government's proffered witness on these grounds.

2. The proffered testimony has a prejudicial effect that outweighs its probative value under [Fed.R.Evid. 403](#).

*8 Defendant argues that the prejudicial effect of the proposed expert's testimony outweighs its probative value and fails the test of [Federal Rule of Evidence 403](#). *Defendant's First Motion to Exclude*, at 3. Defendant does not support this assertion by identifying any prejudicial effects or by analyzing how the testimony's probative value is less weighty than its prejudicial effect. Since the proffered expert's testimony regards evidentiary documents and conclusions that are relevant to the charges being litigated, the only prejudicial effect that might occur is convincing the jurors that defendant committed the crimes of which he is accused. [FRE 403](#) states that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice...." It does not create unfair prejudice to allow presentation of evidence probative of whether the defendant committed the acts of which he is accused. The proffered expert testimony does not fail the test of [Rule 403](#).

The Magistrate Judge concludes that the movant has not established that the proffered expert testimony creates unfair prejudice that outweighs the probative value of the testimony. Consequently, the Magistrate Judge concludes that the movant is not entitled to exclude the proffered expert on these grounds.

3. The government provided insufficient notice under [Fed.R.Crim.P. 16\(a\)\(1\)\(G\)](#).

Defendant argues that the government's letter of November 3, 2008 is "insufficient notice under Federal Rule of Criminal Procedures 16(a)(1)(G)." *Defendant's First Motion to Exclude*, at 2. Defendant claims that the government has provided insufficient notice because it has failed to provide "the requisite bases and reasons for the proffered opinions." *Defendant's Reply Memorandum*, at 9. Defendant supports this argument with the case of *U.S. v. Davis*, which presents an example of inadequate disclosure under [Fed.R.Crim.P. 16\(a\)\(1\)\(G\)](#) where the government's disclosure did not provide the other side with enough information. The disclosed information was insufficient because, if the defense hired its own expert, "he or she would not have been able to analyze the steps that led the government's [experts] to their conclusions." *U.S. v. Davis*, 514 F.3d 596, 613 (6th Cir.2008).

In the case cited by defendant, the material being analyzed was cocaine base. *Davis*, 514 F.3d at 600. The material not disclosed by the government consisted of the chemist notes regarding the testing of the contraband confiscated from the defendant. *Davis*, 514 F.3d at 613. The case at bar is easily distinguished from the scenario presented in *Davis*. Presumably, in *Davis* the government could not turn over to the defense the cocaine base that was tested because of its status as contraband that is illegal to possess. The chemist notes at issue were the material describing the process by which the chemist produced the report declaring that the substance tested was cocaine base. Since defense counsel could not obtain the cocaine base itself, it should have been able to see the next best thing: the notes linking the physical evidence to the report declaring the substance to be

cocaine base. In the case at bar, the government disclosed with its *Response to Motion to Exclude* all of the source data used by the proffered witness in reaching her conclusions. Defendant now possesses the data providing the “bases” for the proffered expert's conclusions. If defendant chooses to hire an expert of his own, that expert will be “able to analyze the steps that led the government's [expert] to [her] conclusions.” *Davis*, 514 F.3d at 613. Defendant already possesses the “reasons” for the proffered expert's opinion because those reasons were disclosed in the government's letter of November 3, 2008.

*9 The Magistrate Judge concludes that the movant has not established that the terms of [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#) have not been met. Consequently, the Magistrate Judge concludes that the movant is not entitled to further [Rule 16\(a\)\(1\)\(G\)](#) disclosure or a hearing on the qualifications or methodologies of the government's proffered witness.

In summary, the government's proffered expert testimony meets the requirements of [Federal Rules of Evidence 401](#) and [702](#) based on the court's preliminary analysis required by [FRE 104\(a\)](#). In addition, the government has disclosed all of the information required by [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#).

III. CONCLUSION

Based on a review of the record and the applicable law governing motions filed pursuant to [Federal Rules of Evidence 702](#), [403](#), and [Federal Rule of Criminal Procedure 16\(a\)\(1\)\(G\)](#), for the reasons previously stated, the Magistrate Judge concludes that the defendant's motion should not be granted.

Accordingly, **IT IS RECOMMENDED** that the motion to exclude the government's expert witness be **DENIED** [DE # 128] and that the request for alternative relief consisting of a perfected 16(a)(1)(G) disclosure and a witness qualification hearing also be **DENIED**.

The Clerk of the Court shall forward a copy of the Proposed Findings of Fact and Recommendation to the respective parties who shall, within ten (10) days of receipt thereof, serve and file timely written objections to the Magistrate Judge's Proposed Findings of Fact and Recommendation with the District Court or else waive the right to raise objections in the Court of Appeals. 28 U.S.C. § 636(b)(1)(B); *Thomas v. Arn*, 728 F.2d 813 (6th Cir.1984), *aff'd*, 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985); *Wright v. Holbrook*, 794 F.2d 1152, 1154–55 (6th Cir.1986); [Fed.R.Civ.P. 6\(e\)](#). A party may file a response to another party's objections within ten (10) days after being served with a copy thereof. [Fed.R.Civ.P. 72\(b\)](#).

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United States District Court, E.D. Texas, Sherman Division.

Theresa HENDRICKS, Individually and as next friend of MH, SH and SH

v.

FORD MOTOR COMPANY.

CASE NO. 4:12-CV-71

|

Signed September 6, 2012

Named Expert: Dr. Dennis J. Seal, Ph.D., P.E.; Jamie L. Petty-Galis, M.S., P.E.; Dr. Timothy P. Rhoades, Ph.D.; Dr. Michelle M. Vogler, Ph.D., P.E.

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ORDER

[AMOS L. MAZZANT](#), United States Magistrate Judge

*1 Pending before the Court are Defendant's Motion to Exclude Testimony of Jaime L. Petty-Galis (Dkt.# 39), Defendant's Motion to Exclude Testimony of Dennis J. Seal, Ph.D. (Dkt.# 40), Plaintiffs' Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43), and Plaintiffs' Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44). Having considered the relevant pleadings, the Court finds the following: (1) Defendant's Motion to Exclude Testimony of Jaime L. Petty-Galis (Dkt.# 39) is DENIED; (2) Defendant's Motion to Exclude Testimony of Dennis J. Seal, Ph.D. (Dkt.# 40) is DENIED; (3) Plaintiffs' Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43) is GRANTED IN PART and DENIED IN PART; and (4) Plaintiffs' Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44) is DENIED.

BACKGROUND FACTS

Plaintiffs assert that on March 7, 2011, Rusty Lamont Hendricks was killed by blunt force [injuries to his head](#), sustained while he performed maintenance work on a minivan in the garage of his home (Dkt. # 58 at ¶¶ 6, 12). Using the original equipment manufacturer (OEM) jack included with the van, Plaintiffs contend that Mr. Hendricks raised the vehicle and began to perform the relevant work. *Id.* at ¶ 8. Plaintiffs assert that the jack failed, allowing the car to fall and causing the injuries to Mr. Hendricks. *Id.* at ¶ 11–12. His wife, Theresa Hendricks, a Plaintiff in this case, had her oldest son call 9–1–1, and both the Plano Police Department and Plano Fire Department responded. *Id.* at ¶ 14–17. Upon arrival, the fire department personnel found Mr. Hendricks with his head and torso under the vehicle (Dkt.# 58, ¶ 17). The fire department used the “jaws of life” to extract Mr. Hendricks's body from under the vehicle. *Id.*

On January 25, 2012, Defendant filed its Motion to Exclude Testimony of Jaime L. Petty–Galis (Dkt.# 39). Plaintiffs filed their response on February 13, 2012 (Dkt.# 51).

On January 25, 2012, Defendant filed its Motion to Exclude Testimony of Dennis J. Seal, Ph.D. (Dkt.# 40). Plaintiffs filed their response on February 13, 2012 (Dkt.# 52).

On January 26, 2012, Plaintiff filed its Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43). Defendant filed its response on February 09, 2012 (Dkt.# 47).

On January 26, 2012, Plaintiff filed its Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44). Defendant filed its response on February 9, 2012 (Dkt.# 48).

LEGAL STANDARD

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590–93 (1993), the Supreme Court instructed courts to function as gatekeepers and determine whether expert testimony should be presented to the jury. Courts act as gatekeepers of expert testimony “to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

*2 The party offering the expert's testimony has the burden to prove by a preponderance of the evidence that: (1) the expert is qualified; (2) the testimony is relevant to an issue in the case; and (3) the testimony is reliable. *Daubert*, 509 U.S. at 590–91. A proffered expert witness is qualified to testify by virtue of his or her “knowledge, skill, experience, training, or education.” *FED. R. EVID.* 702. Moreover, in order to be admissible, expert testimony must be “not only relevant, but reliable.” *Daubert*, 509 U.S. at 589. “This gate-keeping obligation applies to all types of expert testimony, not just scientific testimony.” *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 244 (5th Cir.2002) (citing *Kuhmo*, 526 U.S. at 147).

In deciding whether to admit or exclude expert testimony, the Court should consider numerous factors. *Daubert*, 509 U.S. at 594. In *Daubert*, the Supreme Court offered the following, non-exhaustive list of factors that courts may use in evaluating the reliability of expert testimony: (1) whether the expert's theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the challenged method; and (4) whether the theory or technique is generally accepted in the relevant scientific community. *Id.* at 593–94; *Pipitone*, 288 F.3d at 244. When evaluating *Daubert* challenges, courts focus “on [the experts'] principles and methodology, not on the conclusions that [the experts] generate.” *Daubert*, 509 U.S. at 594.

The *Daubert* factors are not “a definitive checklist or test.” *Daubert*, 509 U.S. at 593. As the Court has emphasized, the *Daubert* framework is “a flexible one.” *Id.* at 594. Accordingly, the decision to allow or exclude experts from testifying under *Daubert* is committed to the sound discretion of the district court. *St. Martin v. Mobil Exploration & Producing U.S., Inc.*, 224 F.3d 402, 405 (5th Cir.2000).

ANALYSIS

Defendant's Motion to Exclude Testimony of Jaime L. Petty–Galis (Dkt.# 39)

Defendant asserts that the Court should exclude three of the four opinions rendered by Plaintiffs' expert Jamie L. Petty–Galis (“Petty–Galis”) on the basis that her opinions lack a reliable methodology and foundation, and are also conclusory and unreliable (Dkt. # 39 at 2). In response, Plaintiffs argue that the sources and bases of Petty–Galis' opinions are reliable. For support, Plaintiffs refer to the extensive experience of Petty–Galis, specifically over twenty (20) years of experience in failure analysis

in mechanical metallurgical engineering (Dkt. # 51, at 7). Further, Plaintiffs argue that the opinions of Petty–Galis are relevant and reliable, and are based not only on her experience in the field, but also on the relevant evidence in this case such as police and fire reports, as well as visual observation and microscopic inspection of the affected jack. *Id.*

First, Defendant argues that the Court should exclude the opinion of Petty–Galis that the jack failed due to bending forces applied under normally anticipated service conditions (Dkt. # 39 at 4). Defendant argues that the opinion of Petty–Galis does not provide a proper foundation or methodology for concluding that “bending forces” under “normally anticipated service conditions” caused the jack to fail. *Id.* Defendant claims that there is no basis for concluding what forces were involved, no basis for determining if those forces were appropriate or not, and no basis for knowing what “normally anticipated service conditions” are. Further, Defendant claims that no testing was done to arrive at these opinions, and that the opinions themselves are simply conclusions.

*3 Plaintiffs respond by defending the opinion, and list the following as sources and bases for this opinion: (1) Plano Police Department Records; (2) Plano Fire Department Records; (3) her personal visual inspection of the involved jack; (4) her microscopic inspection of the involved jack; (5) her visual examination and photo documentation of exemplar OEM jacks, and (6) the NHTSA's Office of Defects Investigation letter regarding Preliminary Evaluation (PE) NO. PE11–033 (Dkt. # 51 at 6). Plaintiffs assert that these sources combined fully allow Petty–Galis to form an expert opinion on the bending forces applied to the jack at the time of the incident.

Defendant also notes that Petty–Galis does not have sources and bases for forming an opinion based on the “normally anticipated service condition” (Dkt. # 39 at 4). Defendant claims that there is no way to know what these conditions may be. Plaintiffs respond by stating that Petty–Galis does not specifically state the exact conditions at the time of service, but rather relies on, and concurs with, the report from the Plano Police Department where it states that at the time of the accident, the jack was, “directly underneath part of the frame which the jack was intended for” (Dkt. # 51 at 12–13.)

“When expert testimony has been challenged, it is incumbent upon the court to conduct a preliminary fact-finding to determine whether the expert is qualified to render the proffered opinions and whether the substance of the testimony is both reliable and relevant.” *Allison v. NIBCO, Inc.*, No. 9:02–CV–172, 2003 WL 25685229, at *1 (E.D.Tex. May 21, 2003). The court must also articulate its basis for admitting expert testimony. See *Rodriguez v. Riddell Sports, Inc.*, 242 F.3d 567, 581 (5th Cir.2001). To be reliable, and therefore admissible under Rule 702 of the Federal Rules of Evidence, expert testimony as to a scientific, technical or other specialized area must: (1) assist the trier of fact to understand the evidence or to determine a fact in issue; (2) be based upon sufficient facts or data; (3) be the product of reliable principles or methods; (4) and have reliably applied the principles and methods to the facts. FED. R. EVID. 702. “The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, et. alia.” *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir.2007).

The party offering the expert testimony has the burden of establishing by a preponderance of the evidence that the challenged testimony is admissible. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998). It is not necessary for the proponent to prove that the expert's testimony is correct, but the proponent must prove the testimony is reliable. *Id.*

The Court finds that in the challenge to this opinion, that “the involved OEM jack failed due to bending forces applied under normally anticipated service conditions,” the challenge fails, as the Plaintiffs have shown proper evidence that the opinion is reliable and relevant, has a foundation on proper sources and bases, and is not conclusory. Petty–Galis is clearly qualified to testify as an expert on this subject matter. Further, the opinion is based on sufficient facts or data contained within the record. In addition, the opinion is the product of reliable principles and methods, namely Petty–Galis' expertise and education in this field. A witness' experience, studies and education, combined with a review of the relevant materials can provide a reliable basis for expert testimony. *Perez v. City of Austin*, No. A–07–CA–044 AWA, 2008 U.S. Dist. LEXIS 36776, *32–33 (W.D.Tex.2008); see also *Pipitone*, 288 F.3d at 247(citing *Kumho*, 526 U.S. at 137 (“no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”)). There is no requirement that Petty–Galis perform

independent testing in order to substantiate her opinions on this subject. Finally, Petty–Galis has reliably applied these principles and methods to this opinion. Therefore, the Court finds Defendant's motion to exclude the opinion of Petty–Galis should be denied on this ground.

*4 Next, Defendant argues that the Court should exclude the second opinion of Petty–Galis, that “the hinge on the jack was deficient in design and/or manufacturing in that it allowed the hinge pin to pull through the base pivot arm under normally anticipated service conditions” (Dkt. # 39–1 at 2). Again, the Defendant notes that there is no reliable foundation or methodology to determine whether the design or manufacturing of the hinge on the jack was deficient (Dkt # 39 at 4–5). In challenging this opinion, Defendant claims that no testing was done, that the opinion was not based upon sufficient facts or data, and that the opinion satisfies none of the *Daubert* factors. Further, the Defendant claims that the opinions are again conclusory and unreliable.

In response, Plaintiffs claim that the opinion that the “hinge pin pulled through the base pivot arm” is not as much an opinion as it is an expert observation (Dkt. # 51 at 8). For support, Plaintiffs claim that this scientific observation is based on Petty–Galis' visual examination and comparison of the OEM jack that failed and other exemplar OEM jacks. Further, Plaintiffs state that this observation would help the triers of fact to understand the issues at hand.

The Court finds that the challenge to the second opinion by Petty–Galis that the hinge on the jack was deficient in design and/or manufacturing in that it allowed the hinge pin to pull through the base pivot arm under “normally anticipated service conditions” (Dkt. # 39–1 at 2), fails, as the Plaintiff has shown that the opinion was properly founded on reliable and relevant bases and sources of information by the expert Petty–Galis, specifically a visual inspection and the experience of Petty–Galis. The opinion is given by a recognized expert with specialized knowledge, the opinion is based on sufficient facts or data, the opinion is the product of reliable principles and methods, and Petty–Galis has reliably applied these principles and methods to this opinion. Therefore, the Court finds Defendant's motion to exclude the opinion of Petty–Galis should be denied on this ground.

Finally, Defendant urges the Court to exclude the opinion of Petty–Galis, that “the bending failure of the involved jack was due to manufacturing and/or design defect that rendered the jack susceptible to sudden structural failure under normal use and without warning.” (Dkt. # 39 at 5). Defendant contends that the phrases “suddenly failed,” “normal use,” and “without warning” have no foundation and are, therefore, unreliable. *Id.* Once again, Defendant claims that the opinion was unsupported by any testing, and is conclusory and unreliable.

In their support of Petty–Galis' opinion, Plaintiffs first note that the phrases, “bending failure,” and, “normal use” have been supported in previous opinions by the physical observations and evidence review of Petty–Galis. Plaintiffs next seek to support the contention of the opinion that the jack suddenly failed without warning. Petty–Galis performed a microscopic review of the affected jack, and compared it to exemplar jacks both through drawings and through visual inspection (Dkt. # 51 at 14–15). From this, she deduced that the jack, “would have been susceptible to sudden structural failure without warning.” (Dkt. # 51 at 15). This deduction is allowed by the Federal Rules of Evidence when it has sound bases and utilizes the expertise of the witness.

The Court finds that the Defendants' Motion to Exclude the Testimony of Jaime Petty–Galis should be denied with respect to this opinion. Petty–Galis made an observation as to the nature of the affected jack, and compared it to exemplars. These examinations, in combination with her extensive experience form a reliable basis to render an opinion of this nature. The opinion is given by a recognized expert with specialized knowledge, the opinion is based on sufficient facts or data, the opinion is the product of reliable principles and methods, and Petty–Galis reliably applied these principles and methods to this opinion. Therefore, the Court finds Defendant's motion to exclude the opinion of Petty–Galis should be denied on this ground.

*5 Based on the foregoing, the Court finds Defendant's motion to exclude the opinions of Petty–Galis (Dkt.# 39) is **DENIED**.

Defendant's Motion to Exclude Testimony of Dennis J. Seal, Ph.D. (Dkt.# 40)

Defendant moves to exclude the testimony of Dennis J. Seal, Ph.D. on the basis that he is not qualified to offer the opinions and his opinions lack a reliable methodology, foundation or supporting testing (Dkt. # 40 at 2). Specifically, Defendant challenges the following opinions by Dr. Seal:

- (1) "It is my expert opinion that Mr. Rusty Hendricks was not aware of the potential for jack failure as he worked on his Ford minivan in his home garage."
- (2) "The unreasonably dangerous conditions and associated failures and negligent acts on the part of Ford Motor Company as related to the issues addressed in this report were more than likely, and with a high degree of scientific certainty, the proximate causes of the failed service jack causing the death of Mr. Rusty Hendricks."
- (3) "... I am of the opinion that the subject jack was hazardous ..."
- (4) Any opinion that the existing warning on the subject jack, owners' manual, or placard were inadequate otherwise rendered the vehicle jack defective or unreasonable dangerous.
- (5) Any opinion that the subject caused in whole or in part the death of Rusty Hendricks.

Id.

As a preliminary matter, Defendant challenges Dr. Seal's qualifications to render these opinions. The Court finds that Dr. Seal is a professional engineer who earned his doctorate in Industrial Engineering/Human Factors and Systems Safety (Dkt. # 52 at 3). He obtained his Bachelor of Arts degree in Psychology, and a Master's degree in Experimental Psychology/Information Processing & Learning (Dkt. # 52 at Ex. B). He has significant experience with product safety standards and design criteria relating to industrial machinery, consumer product design, transportation systems, occupational safety programs, warning labels and instructional material.

Defendant's total argument regarding Dr. Seal's qualifications is that "Dr. Seal is also not qualified to render such an opinion," referring to Dr. Seal's opinion that Mr. Hendricks was not aware of the potential for jack failure (Dkt. # 40 at 4). The preceding sentence in Dr. Seal's report states the following:

The end user cannot be expected to avoid hazards of such probability and severity if appropriate safety information and service procedures are not developed, specifically documented and properly disseminated for review by end users.

(Dkt. # 52 at Ex. A). Defendant's argument ignores Dr. Seal's qualifications to render exactly such an opinion on the human factors involved in the distribution of appropriate safety information. Dr. Seal's is highly qualified to offer opinions regarding this subject matter, and Defendant's argument in this regard is unfounded.

Defendant challenges the remaining opinions as irrelevant and unreliable. To be reliable, and therefore admissible under [Rule 702 of the Federal Rules of Evidence](#), expert testimony as to a scientific, technical or other specialized area must: (1) assist the trier of fact to understand the evidence or to determine a fact in issue; (2) be based upon sufficient facts or data; (3) be the product of reliable principles or methods; (4) and have reliably applied the principles and methods to the facts. [FED. R. EVID. 702](#).

*6 Defendant does not argue that Dr. Seal's opinions will not assist the trier of fact to understand the evidence or determine a fact in issue, or that his opinions are not based on sufficient facts or data. The Court finds that Dr. Seal's opinions are clearly relevant to aid the jury in determining material fact issues. In addition, Dr. Seal's opinions are based on records from the Plano Police Department, Ford Freestar Minivan Advertisements and Brochures for 2004 Model Year, Scheduled Maintenance Guide for Ford Freestar Minivan 2004 Model Year, Purchase Invoice for R. Hendricks Ford Freestar Minivan, Photographs of

Advertised Ford Freestar Minivan and Subject Ford Freestar Minivan Service Jack, Ford Engineering Material Specification, Tire Changing Instructions and Jack and Spare Tire Stowage, Ford Service Jack Label and Graphics, Ford Engineering Material Specifications, and Ford Release Dimensional Drawing for Revised Jack Bracket and Tie-Down (Dkt. # 52 at Ex. A). The Court finds that Dr. Seal's opinions are based on sufficient facts and data.

Therefore, the Court must determine if Dr. Seal's opinions are the products of reliable principles and methods, and if they were reliably applied to the facts of this case. Dr. Seal states in his report that he relied on the Hazard Mode and Effects Analysis ("HMEA"), which is a standard practice in which manufacturers use a Hazard Mode and Effect Analysis worksheet and decision matrix for "listing all hazards and filing as a database for the purpose of tracking and the ultimate elimination, control, or the development of warning (i.e., operations and maintenance) for the identification of specific hazards" (Dkt. # 52 at Ex. A). Dr. Seal states that products found to be hazardous during operation or service will require design modifications or warning labels. The adequacy of the warnings is determined in reference to both the content of the warning and the location. In addition, Dr. Seal relied on Failure Modes and Effects Analysis ("FMEA"), which he describes as "another procedure for isolating potential failure modes (e.g. parts, components) and for recommending corrective actions based on derived reliability data." *Id.* Dr. Seal states,

Both the HMEA and FMEA are accepted methods of hazard identification in the engineering field for purposes of (end user) risk mitigation. The ultimate objective of both analytical approaches is to reduce the probability of failure occurrence, lower the severity of the consequences, and eliminate the risk of injury or death due to system related hazards or component failures.

Id. Defendant does not challenge the general acceptance of these methodologies or ways of evaluating risk factors. Therefore, the Court finds that Dr. Seal's opinions are the products of reliable principles and methods.

However, Defendant does challenge Dr. Seal's conclusions. The Court finds that Dr. Seal's principles and methods are reliably applied to the facts of this case. Using the HMEA, FMEA, and standards outlined by the American national Standards Institute, Dr. Seal evaluated the facts as known to him from his review of the materials in this case. When evaluating *Daubert* challenges, courts focus "on [the experts'] principles and methodology, not on the conclusions that [the experts] generate." *Daubert*, 509 U.S. at 594. The Court finds that Dr. Seal's is highly qualified to render an opinion on this subject, that he based his opinions on sufficient facts or data, applied reliable principles and methods to form his opinions, and reliably applied those principles and methods to the facts of this case.

Therefore, the Court finds that Defendant's motion to exclude the testimony of Dr. Seal (Dkt.# 40) is **DENIED**.

Plaintiffs' Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43)

Plaintiffs assert that the Court should exclude in its entirety the opinions of Defendant's expert Dr. Timothy P. Rhoades ("Dr. Rhoades") on the basis that Dr. Rhoades is not qualified to render his opinion, that Dr. Rhoades' opinions lack proper foundation and methodology, and his opinions are conclusory (Dkt. # 43 at 5–6). Specifically, Plaintiffs challenge nine opinions contained within Dr. Rhoades' report, as follows:

- *7 (1) "At this time it is not exactly clear why Mr. Hendricks was under the vehicle, but the best available information about the accident indicates he was using a wrench in a manner that applied a force toward the front of the vehicle."
- (2) "In addition, available information from police photographs indicates"
- (3) "The parking brake was not used"
- (4) "That the left rear tire was not effectively blocked"

- (5) “The 2004 Ford Freestar Owner's Guide includes organizational features and an index to help users find information.”
- (6) “New 2004 Ford Freestars included a two-sided 8.5" × 11" laminated card with Tire Changing Instructions on one side and Jack and Spare Tire Stowage information on the other side that could be removed from the jack storage area and be used as a reference at the location the jack would be used.”
- (7) “Warning instructions provided with 2004 Freestars are also found in other sources such as do-it-yourself service manuals and various Internet sites. For example, the Chilton© repair manual for 2004 Freestars provides warnings to not rely on a jack when working under a vehicle.”
- (8) “In this case there is no indication that the procedure used by Mr. Hendricks to gain access beneath the vehicle was based on warnings or instructions provided by Ford. In fact, the unsafe method used by Mr. Hendricks was contrary to warnings and instructions provided by Ford, and may have been his practice before his purchase of the subject vehicle.”
- (9) “Ford Motor Company provided clear warnings and instructions with 2004 Freestars regarding use of the jack. This information included warnings and instructions to apply the parking brake, block (in both directions of the wheel that is diagonally opposite), and to not get under the vehicle. As described below, warnings and instructions were provided within the Owner's Guide, on a laminated card, and on labeling on the jack. Mr. Hendricks's accident would not have occurred if these instructions and warnings had been followed. Regarding vehicle maintenance, Ford Motor Company provided clear instructions to set the parking brake and block the wheels when working with the engine on or off.”
- (Dkt. # 43 at 4–5). Defendant argues that Dr. Rhoades qualifies as a human factors and warnings expert, and that Dr. Rhoades' opinions are reliable and based on a solid evidentiary foundation (Dkt. # 47 at 5–12). Defendant categorizes Plaintiff's challenges to Dr. Rhoades' opinions into two groups: (1) opinions or statements associated with the accident and (2) opinions or statements concerning the warnings and instructions accompanying the vehicle and the jack (Dkt # 47 at 6).

Without identifying specific areas or opinions where Plaintiffs believe Dr. Rhoades lacks qualifications, Plaintiffs challenge Dr. Rhoades' designation as an expert witness in one sentence: “Dr. Timothy Rhoades is also not qualified to render such an opinion” (Dkt. # 43 at 5). Defendant refers to the extensive experience of Dr. Rhoades in the engineering field and his educational pedigree as a student and teacher of Industrial & Operations Engineering to establish his expertise in human factors, instructions, and warnings. (Dkt. # 47 at 5–6).

The Court agrees that Dr. Rhoades qualifies as an expert on human factors engineering, product and occupational safety, and warnings and instructions design. An expert must be qualified to testify by virtue of his or her “knowledge, skill, experience, training, or education.” [FED. R. EVID. 702](#). Dr. Rhoades has a Ph.D., Master's, and Bachelor's degree in Industrial & Operations Engineering from the University of Michigan (Dkt. # 47, Ex. B at 1). He has worked in the engineering field for over thirty (30) years and is an Adjunct Assistant Professor at the University of Michigan since 1995, teaching courses in Occupational and Product Safety Management within the Department of Industrial & Operations Engineering. *Id.* He has published numerous peer-reviewed articles and conducted professional presentations on human factors and warnings. *Id.* Further, Dr. Rhoades has served as a member on a subcommittee with the American National Standards Institute (ANSI) regarding “Product Safety Information in Product Manuals, Instructions, and Other Collateral Material.” *Id.* Therefore, the Court finds Dr. Rhoades possesses the knowledge, skill, experience, training, and education to qualify as an expert on human factors engineering, product and occupational safety, and warnings and instructions design.

***8** Plaintiff specifically challenges nine opinions expressed in Dr. Rhoades' opinion of the incident (Dkt.# 47, Ex. A). Opinions one, two, and four are characterized as statements and opinions related to the accident:

- (1) “At this time it is not exactly clear why Mr. Hendricks was under the vehicle, but the best available information about the accident indicates he was using a wrench in a manner that applied a force toward the front of the vehicle.”

(2) “In addition, available information from police photographs indicates”

(4) “That the left rear tire was not effectively blocked”

(Dkt. # 47, Ex. A at 4). While challenging these portions of the opinion, Plaintiffs do not explain why these opinions should be stricken other than a general challenge to a lack of methodology and that the opinions are conclusory (Dkt. # 43 at 5). Defendant argues that these conclusions are based on observations of evidence Dr. Rhoades examined, including:

(1) Scene photographs of a light shining down into the engine compartment of the minivan with a wrench hanging down from the engine compartment;

(2) Scene photographs of an open toolbox;

(3) Scene photographs of firewood in front of both the left front and rear tires and a brick behind the left rear tire;

(4) And a medical examiner's records report that states Mr. Hendrix was removed from underneath the vehicle, among other photographs and reports.

(Dkt. # 47 at 6–7, Ex. C).

A witness' experience, studies, and education, combined with a review of the relevant materials, can provide a reliable basis for expert testimony. *Perez*, 2008 U.S. Dist. LEXIS 36776, at *32–33; *see also Pipitone*, 288 F.3d at 247(citing *Kumho*, 526 U.S. at 137 (“no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”)). Further, Plaintiffs concern regarding the testimony of Dr. Rhoades may be properly addressed in cross-examination. “[T]he trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system.” *Allison*, 2003 WL 25685229, at *1 n.1 (citation omitted). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Id.* (quoting *Daubert*, 509 U.S. at 596). Here, Dr. Rhoades' conclusions are drawn from his scientific experience as an engineer, his education, and his observations made upon the review of relevant materials. Defendant may properly cross-examine Dr. Rhoades on his opinions, the materials he relied upon in forming his opinions, and the reliability of his opinion at trial; however, this is no reason to exclude these opinions of Dr. Rhoades. *See Allison*, 2003 WL 25685229, at *1 n.1. Therefore, the Court finds Plaintiff's motion to exclude Dr. Rhoades' opinions one, two, and four are denied.

Plaintiffs next challenge Dr. Rhoades' opinion that “the parking brake was not used” (Dkt. # 43 at 4, Ex. A at 4). Plaintiffs argue that Dr. Rhoades assumes the parking brake was not set because there is not a photograph or document that shows the parking brake was set. Defendant explicitly confirms this reasoning as evidence that the parking brake was not set (Dkt. # 47 at 7).

***9** The party offering the expert testimony has the burden of establishing by a preponderance of the evidence that the challenged testimony is admissible. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998). It is not necessary for the proponent to prove that the expert's testimony is correct, but the proponent must prove the testimony is reliable. *Id.* To be reliable, and therefore admissible under [Rule 702 of the Federal Rules of Evidence](#), expert testimony as to a scientific, technical or other specialized area must: (1) assist the trier of fact to understand the evidence or to determine a fact in issue; (2) be based upon sufficient facts or data; (3) be the product of reliable principles or methods; (4) and have reliably applied the principles and methods to the facts. [FED. R. EVID. 702](#). “The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion.” *Knight*, 482 F.3d at 355.

A parking brake can only be in two positions: set or not set. Dr. Rhoades bases his opinion that the parking brake was not set on nothing more than an absence of proof that the parking brake was set (Dkt. # 47 at 7). However, without photographs or investigation reports to confirm that the parking brake was or was not set, there is a fifty-fifty chance of either possibility. Defendant presents no evidence, as none exists, to show that the parking brake was not set, and therefore fails to show by a

preponderance of the evidence that Dr. Rhoades' opinion is reliable. Therefore, the Court finds that Plaintiff's motion to exclude Dr. Rhoades's opinion that "the parking brake was not used" is granted.

Plaintiff next challenges the foundation and methodology of Dr. Rhoades' opinions numbered five through nine regarding opinions or statements concerning the warnings and instructions accompanying the vehicle and the jack:

- (5). "The 2004 Ford Freestar Owner's Guide includes organizational features and an index to help users find information."
 - (6). "New 2004 Ford Freestars included a two-sided 8.5" × 11" laminated card with Tire Changing Instructions on one side and Jack and Spare Tire Stowage information on the other side that could be removed from the jack storage area and be used as a reference at the location the jack would be used."
 - (7). "Warning instructions provided with 2004 Freestars are also found in other sources such as do-it-yourself service manuals and various Internet sites. For example, the Chilton repair manual for 2004 Freestars provides warnings to not rely on a jack when working under a vehicle."
 - (8). "In this case there is no indication that the procedure used by Mr. Hendricks to gain access beneath the vehicle was based on warnings or instructions provided by Ford. In fact, the unsafe method used by Mr. Hendricks was contrary to warnings and instructions provided by Ford, and may have been his practice before his purchase of the subject vehicle."
 - (9). "Ford Motor Company provided clear warnings and instructions with 2004 Freestars regarding use of the jack. This information included warnings and instructions to apply the parking brake, block (in both directions of the wheel that is diagonally opposite), and to not get under the vehicle. As described below, warnings and instructions were provided within the Owner's Guide, on a laminated card, and on labeling on the jack. Mr. Hendricks's accident would not have occurred if these instructions and warnings had been followed. Regarding vehicle maintenance, Ford Motor Company provided clear instructions to set the parking brake and block the wheels when working with the engine on or off."
- (Dkt. # 43 at 6). Specifically, Plaintiffs claim Dr. Rhoades cites to no known accepted guides to support that instructions were "clear" or that an organizational feature or index was employed. *Id.* Further, Plaintiffs assert Dr. Rhoades makes no reference to an engineering standard that would confirm the clarity of the laminate card or the symbols on the jack. *Id.*

***10** Defendant argues that the first three opinions are factual observations while the final two opinions are the expert's own opinion (Dkt. # 47 at 9–11). Defendant also claims Dr. Rhoades relied upon recognized standards promulgated by the ANSI and the International Standards Organization (ISO).

The Court agrees that opinions five, six, and seven are factual observations. Dr. Rhoades asserts that the vehicle comes with an Owner's Guide, a factual observation (Ex. A at 5). The opinion that the Owner's Guide includes "organizational features and an index to help user find information" can be properly attributed to Dr. Rhoades' experience, education, and observation as an expert in warnings and instruction design. Next, opinion six is wholly a factual observation as a two-sided laminate card with changing tire instructions can be removed from the jack storage area and is portable so as to be useful at the location of the tire. Finally, opinion seven states where the warnings and instructions can be found other than the Owner's Guide, including commercially available repair manuals and the Internet; this too is a factual observation.

Besides relying on his experience, education, and training, Dr. Rhoades also relied on recognized standards of the ANSI and the ISO. In his report, Dr. Rhoades cites these standards, opining:

ANSI Z535.4–2007 expressly permits the use of ISO standard 3864–2, which includes provisions for wordless labels. ANSI Z535.4–2007 also acknowledges that, at this time, the ANSI Z535 and ISO 3864 standards are not completely harmonized. Conformance with the ANSI Z535 standards is voluntary and these standards are not specific to the automotive industry. It should also be noted that conformance

with the ANSI Z535.4 format does not reliably affect behavioral compliance with warnings (Young et al., 2002).

(Dkt. # 47, Ex. A at 8). In his report, Dr. Rhoades claims to have performed his own testing using the ANSI Z535.3 standards for this litigation to support his opinion that Ford's symbol warnings met the comprehension requirements of the ANSI standards (Dkt. # 47, Ex. A at 9).

The Court finds that in the challenge to opinion eight, that Mr. Hendricks' access beneath the vehicle was “contrary to warnings and instructions provided by Ford,” the challenge fails, as the Defendants have shown proper evidence that the opinion is reliable and relevant, has a foundation on proper sources and bases, and is not conclusory. The opinion is given by a recognized expert with specialized knowledge, the opinion is based on sufficient facts or data, the opinion is the product of reliable principles and methods, and Dr. Rhoades has reliably applied these principles and methods to his opinion.

The Court finds that the challenge to opinion nine of Dr. Rhoades that “Ford Motor Company provided clear warnings and instructions with 2004 Freestars regarding use of the jack” and that “Mr. Hendricks' accident would not have occurred if these instructions and warnings had been followed” fails, as the Defendant has shown that the opinion was properly founded on reliable and relevant bases and sources of information by the expert Dr. Rhoades, specifically the factual observations expressed in challenged opinions numbers five, six, and seven. The opinion is given by a recognized expert with specialized knowledge, the opinion is based on sufficient data or facts, the opinion is the product of reliable principles, and Dr. Rhoades has reliably applied these principles and methods to this opinion.

***11** Therefore, the Court finds that Plaintiff's motion to exclude the testimony of Dr. Rhoades' opinions five through nine should be denied. Based on the foregoing, the Court finds that Plaintiffs' Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43) is **GRANTED IN PART and DENIED IN PART**.

Plaintiffs' Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44)

Plaintiffs argue generally that Michelle Vogler, Ph.D. (“Dr.Vogler”) is not qualified to testify as an expert in this matter, conducted no tests, did not inspect the vehicle, and fails to state the methodology relied upon in her analysis.

As a preliminary matter, the Court finds that Dr. Vogler is highly qualified to testify as an expert in this matter. Plaintiffs' conclusory statement that she is not qualified to render expert testimony is clearly unsupported. Dr. Vogler is a licensed and registered professional engineer, has a Ph.D. in mechanical engineering from Stanford University, a master's degree in mechanical engineering from the University of Santa Clara, and a bachelor's degree in mechanical engineering from Michigan State University (Dkt. # 48 at 5). In addition, Dr. Vogler has thirty years of working experience in engineering. The Court finds that Dr. Vogler is qualified to testify on the matters in this case.

Plaintiffs' challenge the remaining opinions as irrelevant and unreliable. To be reliable, and therefore admissible under [Rule 702 of the Federal Rules of Evidence](#), expert testimony as to a scientific, technical or other specialized area must: (1) assist the trier of fact to understand the evidence or to determine a fact in issue; (2) be based upon sufficient facts or data; (3) be the product of reliable principles or methods; (4) and have reliably applied the principles and methods to the facts. [FED. R. EVID. 702](#).

First, the Court finds that Dr. Vogler's opinions will assist the trier of fact to understand evidence regarding the operation and failure of the jack, or to determine a fact in issue in the case. Second, the Court finds that Dr. Vogler's opinions are based upon sufficient facts or data. Dr. Vogler's opinions are based on the pleadings in this case, expert opinions of Plaintiff's experts, accident report by the Plano Police Department and Plano Fire Department, Accident Scene Photographs, Medical Records, and photographs and information obtained regarding the subject jack and vehicle (Dkt. # 48 at Ex. A, pp. 2–3).

Therefore, the Court must determine whether Dr. Vogler's opinions are the product of reliable principles or methods. Three of the challenged opinions are as follows:

- (1) "... [T]here was separation of the jack lower arms rear mounts to the pivot pins, however the forward mounts remain attached and load bearing."
- (2) "Simply because a joint can be overloaded to the point of separation does not make it a defective joint."
- (3) "There is no evidence of a design or manufacturing defect in the subject assembly that contributed to the outcome of this accident."

(Dkt. # 44 at 5–6). However, the Court finds that these are not opinions, but rather constitute observations made by Dr. Vogler in the process of her examination of the materials used in forming her opinions. Therefore, these statements should not be excluded on this basis.

*12 Dr. Vogler explains that her remaining opinions are based on an "accident reconstruction analysis" to evaluate the evidence found at the accident scene (Dkt. # 52 at Ex. D, p. 3). Dr. Vogler states that her analysis was based on fundamental techniques and principles of mechanical engineering and physics regularly and routinely relied upon by experts in the field of accident reconstruction. *Id.* Further, Dr. Vogler clearly relies on her extensive experience in this field to reach her conclusions. A witness' experience, studies and education, combined with a review of the relevant materials can provide a reliable basis for expert testimony. *Perez*, 2008 U.S. Dist. LEXIS 36776, *32–33; *see also Pipitone*, 288 F.3d at 247(citing *Kumho*, 526 U.S. at 137 ("no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.")). Therefore, the Court finds that Dr. Vogler's testimony is based on reliable principles and methods, which were reliably applied to the facts of this case.

Based on the foregoing, the Court finds that Plaintiffs' Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44) is **DENIED**.

CONCLUSION

For the foregoing reasons, the Court finds that Defendant's Motion to Exclude Testimony of Jaime L. Petty–Galis (Dkt.# 39) is **DENIED**.

The Court further finds that Defendant's Motion to Exclude Testimony of Dennis J. Seal, Ph.D. (Dkt.# 40) is **DENIED**.

The Court further finds that Plaintiffs' Amended Motion to Exclude Testimony of Dr. Timothy P. Rhoades (Dkt.# 43) is **GRANTED IN PART** and **DENIED IN PART**.

The Court further finds that Plaintiffs' Amended Motion to Exclude Testimony of Michelle Vogler, Ph.D. (Dkt.# 44) is **DENIED**.

IT IS SO ORDERED.

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United States District Court, M.D. Pennsylvania.

Heidi HANRECK and Raymond Andrarowski, Plaintiffs,

v.

WINNEBAGO INDUSTRIES, INC., Defendant.

Civil No. 1: 16-cv-01163

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Signed 03/27/2019

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MEMORANDUM

SYLVIA H. RAMBO, United States District Judge

*1 In the instant matter, Plaintiffs Heidi Hanreck and Raymond Andrarowski (“Plaintiffs”) seek monetary damages for breach of express and/or implied warranties in violation of the Magnuson-Moss Warranty Act, 15 U.S.C. 2301, *et seq.* (“MMWA”) and in violation of state consumer protection laws, related to the sale of a recreational vehicle sold by Defendant Winnebago Industries, Inc. (“Defendant”). Presently before the court is Defendant's motion for summary judgment as to all counts (Doc. 37,) as well as several motions *in limine* filed by both parties. For the reasons that follow, Defendant's motion will be granted in part and denied in part.

I. Background

On April 4, 2015, Plaintiffs purchased a 2013 Winnebago Adventurer Model 35P Recreational Vehicle (“RV”) from “Camping World of Hudson Valley” in Kingston, New York (“Camping World”). (Doc. 37-1, ¶ 1.) The RV was delivered to Plaintiffs on April 30, 2015. (Doc. 80, ¶ 1.) Plaintiffs registered their vehicle, although it is unclear if they did so upon purchase or receipt, and Defendant provided a New Vehicle Limited Warranty (the “Warranty”). In pertinent part, the Warranty guaranteed that Defendant or one of its authorized dealers would provide for the repair or replacement of component parts deemed defective in material or workmanship within the first twelve months of ownership of the RV. (Doc. 37-1, ¶¶ 16-20.) In the event that the repairs are unsatisfactory or impractical at an authorized dealer, the Warranty provides that Defendant may request that the vehicle be transported to one of Defendant's factories for more extensive repairs. (*Id.* at 21; Doc. 80, ¶ 22.) If the customer refuses this request, the Warranty is deemed void with respect to that particular repair or issue. (*Id.* at 22.)

After taking possession of the RV, Plaintiffs “established residency” in Florida, and registered the RV in that state. (Doc. 80, ¶¶ 12-13.) Although Plaintiffs disagree that they were living in the RV full time or considered it their permanent residence, they did not have a physical home and actually sold their last physical home immediately after purchasing the RV. After registering the vehicle, they embarked upon a yearlong sojourn across the continental United States. Their journey was less than stellar. In sum, they presented the RV for repair under the Warranty at the following dates and locations:

Camping World Kingston, NY 4/4/15 - 4/30/15

Lenrich Mobile Services, NY 6/1/15

Camping World Hendersonville, NC 9/3/15

Camping World Harrisburg, PA 9/15/15 - 10/1/15

Camping World Belville Port Clinton, OH 10/2/15

Camping World of Belville, MI 10/3/15

Camping World Albuquerque, NM 11/6/15

Camping World Tucson, AZ 11/25/15 - 12/1/15

Camping World Mesa, AZ 12/14/15

Camping World Newhall, CA 2/22/16 - 2/26/16

(Doc. 80, ¶ 27.) On or around December 3, 2015, Plaintiffs apparently contacted Defendant directly for the first time. (Doc. 37-1, ¶ 30.) Plaintiffs exchanged several emails with Defendant's representative while travelling through New Mexico and Arizona. (*Id.* at ¶¶ 31-35.) Despite combing the desert for an acceptable facility, Plaintiffs were unsatisfied with the repairs performed by Defendant's authorized dealers. (*Id.* at ¶ 33.) Defendant requested via email that they schedule factory repairs at Defendant's Eugene, Oregon repair site on April 7, 2016, which was apparently chosen to accommodate Plaintiffs' plans to travel from Arizona up the western coast of the United States. (*Id.*) When Defendant's representative followed up with Plaintiffs regarding the April factory repair, Plaintiffs informed them that they were declining the factory repair and intended to pursue legal action against Defendant. (*Id.* at ¶ 35.)

*2 On June 15, 2016, Plaintiffs filed the instant action (Doc. 1), and subsequently filed an amended complaint on July 10, 2016 (Doc. 7).¹ Defendants filed a motion for summary judgment as to all counts on April 27, 2018. (Doc. 37.) Plaintiffs filed their brief in opposition on June 18, 2018, (Doc. 81), and Defendants filed their reply brief on July 2, 2018 (Doc. 82). Accordingly, the matter has been fully briefed and is ripe for disposition.

II. Legal Standard

In considering a motion for summary judgment, a court may dismiss claims that do not present a “genuine dispute as to any material fact” and for which a jury trial would be an empty and unnecessary formality. *Fed. R. Civ. P. 56(a)*. In order to prevail on a motion for summary judgment, the moving party must produce “affirmative evidence, beyond the allegations of the pleadings,” in support of its right to relief. *Pappas v. City of Lebanon*, 331 F. Supp. 2d 311, 315 (M.D. Pa. 2004); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The court must view the evidence “in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor.” *Thomas v. Cumberland Cty.*, 749 F.3d 217, 222 (3d Cir. 2014). This evidence must be adequate, as a matter of law, to sustain a judgment in favor of the non-moving party on the claims. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-57 (1986).

Both parties must support their factual assertions by “citing to particular parts of materials in the record” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute.” *Fed. R. Civ. P. 56(c)*. Rule 56(e) allows the court to deem undisputed any fact not properly countered by record evidence. *See Fed. R. Civ. P. 56(e)(2)*. The nonmoving party must then “go beyond the pleadings by way of affidavits, depositions ... or the like in order to demonstrate specific material facts which give rise to a genuine issue.” *Celotex*, 477 U.S. at 324. In considering a motion for summary judgment, the court is not to engage in credibility determinations or the weighing of evidence. *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992), *cert. denied* 507 U.S. 912 (1993). Instead, “[i]nferences should be drawn in the light most

favorable to the non-moving party, and where the non-moving party's evidence contradicts the movant's, then the non-movant's must be taken as true." *Id.*

III. Discussion

A. Choice of Law

The parties disagree as to whether Pennsylvania or New York law applies. Defendants argue that New York law applies because the sale and warranty were both established in New York, while Plaintiffs argue that Pennsylvania law should apply because no "true conflict" exists between the relevant New York and Pennsylvania substantive law, and, thus, the law of the forum state should apply.

*3 A federal court exercising diversity jurisdiction must apply the choice of law rules employed by the state in which it sits. *Klaxon v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). Pennsylvania's choice of law rules involve a combined "significant relationship test" and a "government interest analysis". *Carrick v. Zurich-American Ins. Grp.*, 14 F.3d 907, 909 (3d Cir. 1994). As a prerequisite, however, the court must first determine if a "true conflict" exists between the relevant laws of New York and Pennsylvania.

In Pennsylvania, different state laws may apply to different issues within a case. *Berg Chilling Sys., Inc. v. Hull*, 435 F.3d 455, 462 (3d Cir. 2006). If the jurisdictions' laws are the same, there is no conflict, and the court's choice of law inquiry ends. *Hammersmith v. TIG Ins. Co.*, 480 F.3d 220, 230 (3d Cir. 2007). If there are relevant differences between the laws, an actual conflict exists, and the court must then determine if the conflict is "true," "false," or "unprovided-for." *Id.* A "true" conflict exists only if "both jurisdictions' interests would be impaired by the application of the other's laws." *Id.* If the court identifies a true conflict, it "must then determine which state has the 'greater interest in the application of its law.'" *Id.* at 231 (quoting *Cipolla v. Shaposka*, 267 A.2d 854, 855 (Pa. 1970)).² If a true conflict exists, the court must "determine which state has the greater interest in the application of its law" by using "a combination of the approaches of both the Restatement II (contacts establishing significant relationships) and 'interests analysis' (qualitative appraisal of the relevant States' policies with respect to the controversy)." *Hammersmith*, 480 F.3d at 231 (internal quotations omitted). Accordingly, the court will first determine if a true conflict exists as to each claim asserted by Plaintiffs.

i. Magnuson-Moss Warranty Act and Implied Warranty Claim

*4 The MMWA, 15 U.S.C. § 2301 *et seq.*, provides a private right of action in federal court for consumers who are damaged by a warrantor's failure to comply with the terms of a written or implied warranty. See *Fleisher v. Fiber Composites, LLC*, No. 12-cv-1326, 2012 WL 5381381 (E.D. Pa. 2012). Under the MMWA:

[A] consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this title [15 USCS §§ 2301 *et seq.*], or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief.

15 U.S.C. 2310(d)(1). A claim under the MMWA relies on the underlying state law claim. *Id.* The MMWA establishes a remedy under federal law but does not create an independent cause of action from the underlying breach. *In re Shop-Vac Mktg. & Sales Practices Litig.*, 964 F. Supp. 2d 355, 361 (M.D. Pa. 2013) (quoting *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1022 (9th Cir. 2008) ("this court's disposition of the state law warranty claims determines the disposition of the [MMWA] claims."); see also *Woolums v. Nat'l RV*, 530 F. Supp. 2d 691, 696 (M.D. Pa. 2008), as amended (Feb. 1, 2008) ("The protections of [the MMWA] are broader than those provided by the [Uniform Commercial Code]"); compare 15 U.S.C. §§ 2301, 2310(d)(2)

(allowing plaintiff to recover actual damages, costs, and attorney's fees for breach of warranties and other service contracts), with 13 Pa. [C.S.] §§ 2313-2315, 2703-2715 (“permitting recovery of actual damages for breach of warranty.”) Accordingly, for purposes of the choice of law analysis, the court looks to the underlying state law for breach of warranty claims.

The parties agree that there is an actual conflict between Pennsylvania and New York on implied warranties of merchantability because Pennsylvania does not require privity of contract, but New York does. Compare *Haag v. Hyundai Motor Am.*, 969 F. Supp. 2d 313 (W.D. N.Y. 2013); with *Williams v. W. Penn Power Co.*, 467 A.2d 811 (Pa. 1983). The parties, however, dispute whether this amounts to a “true conflict.” Plaintiffs argue that there is a false conflict as to the states' implied warranty laws because only Pennsylvania's interests would be impaired if its implied warranty law were not applied. They claim that New York's privity requirement was meant to protect New York corporations from excess liability, i.e. New York has an interest in ensuring that a New York manufacturer is not subjected to suit by a party that purchases a product from a third-party seller. Conversely, Plaintiffs suggest, Pennsylvania's interest in protecting consumers is much broader, and Pennsylvania law protects all consumers regardless of their residency within the Commonwealth. The court agrees with Defendants that Plaintiffs' argument is speculative and is without support in legislative history or case law. Plaintiffs cite to no New York case law where a nonresident manufacturer was denied the protections of New York implied warranty law in contrast to a resident manufacturer. Indeed, such a position may be unconstitutional. See *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 272 (1984) (collecting cases that have invalidated discriminatory state statutes enacted for protectionist purposes).

*5 Instead, New York seems to have an interest in limiting manufacturer liability while Pennsylvania does not. New York has consumer protection laws, as does Pennsylvania, so it is not as if New York has an anti-consumer policy as opposed to Pennsylvania's pro-consumer viewpoint. Instead, it merely seems that New York law is somewhat protective of manufacturers. This position is underscored by the fact that the privity requirement applies only to cases “where the only loss alleged is economic” as opposed to cases in which a plaintiff alleges bodily harm or other noneconomic losses. *Catalano v. BMW of N. Am., LLC*, 167 F. Supp. 3d 540, 556 (S.D.N.Y. 2016). The Pennsylvania Supreme Court, in contrast has held that there is “no current societal interest [] served by permitting the manufacturer to place a defective product in the stream of commerce and then to avoid responsibility for damages caused by the defect.” *Salvador v. Atl. Steel Boiler Co.*, 319 A.2d 903, 907 (Pa. 1974). Thus, the interests of New York and Pennsylvania conflict with respect to the imposition of liability on a manufacturer. See *Powers v. Lycoming Engines*, 272 F.R.D. 414, 421 (E.D. Pa. 2011) (finding a true conflict between New York and Pennsylvania warranty laws because New York required privity of contract and Pennsylvania does not); see generally *Hammersmith*, 480 F.3d at 230 (citing *Cipolla v. Shaposka*, 267 A.2d 854, 856 (1970) (deciding to “undertake a deeper analysis” because the plaintiff “is a resident of Pennsylvania which has adopted a plaintiff-protecting rule” and the defendant “is a resident of Delaware which has adopted a defendant-protecting rule”)). Accordingly, the court finds that a true conflict exists between New York and Pennsylvania's implied warranty law.

Because a true conflict exists, the court will look to the two-pronged Pennsylvania conflict of laws analysis. The first prong applies the Restatement (Second) of Conflict of Laws approach. Under Section 188(2) (the general provision governing contracts), of the Restatement (Second) of Conflict of Laws, the court must look to the following contacts:

- (1) the place of contracting; (2) the place of negotiation of the contract; (3) the place of performance;
- (4) the location of the subject matter of the contract; and (5) the domicile, residence, nationality, place of incorporation and place of business of the parties.

Hammersmith, 480 F.3d at 233 (internal citations omitted). If the place of negotiation and performance are the same, that state's law will normally be the more significant. Restatement (Second) of Conflict of Laws § 188(3) and cmt. f (1971). Here, the analysis under the Restatement is straightforward. The contract was entered into in New York, negotiated in New York, and the performance and the subject matter of the contract are located in New York, e.g. delivery, took place in New York.³ The

remaining factor, the residence of the parties, is neutral as neither party is resident, domiciled, or incorporated in Pennsylvania or New York.

In the second half of the Pennsylvania conflicts of law analysis, the court must consider the “interests and policies that may be validly asserted by each jurisdiction.” *Melville v. Am. Home Assur. Co.*, 584 F.2d 1306, 1311 (3d Cir. 1978). Typically, a state will be considered to have an interest in having its law applied to its residents or to protect its residents. See *Powers*, 272 F.R.D. at 423-24. In this case, neither party is a resident of Pennsylvania or New York. Insofar as either state has an interest in furthering their respective policies of consumer protection or limiting manufacturer liability, there is no indication that the conflicts of law analysis would give preference to one policy over another. Accordingly, under the Pennsylvania conflict of laws analysis, New York law applies to Plaintiff’s implied warranty claim.

ii. Magnusson-Moss Warranty Act and Express Warranty

Defendants argue that a true conflict exists between Pennsylvania and New York express warranty law because, under Pennsylvania law, a limited warranty entitles a plaintiff to recovery under the MMWA, see *Woolums v. National RV*, 530 F. Supp. 2d 691 (M.D. Pa. 2008), while New York law disallows a refund or replacement remedy for a breach of a limited warranty, *Pyskaty v. Wide World of Cars, LLC*, 856 F.3d 216, 223-24. The MMWA requires each consumer warranty to designate whether it is “full” or “limited.” 15 U.S.C. § 2303. A warranty shall be “full” if it meets the criteria set forth in Section 2304 of the MMWA, which requires (1) that the seller remedy any “defect, malfunction, or failure to conform” to the warranted product standards; (2) the warranty may not impose a limitation of the duration of any implied warranty; (3) the warranty may not exclude or limit consequential damages for breach of any written or implied warranty unless the exclusion or limitation appears “conspicuously” on the warranty; and (4) “if the product (or a component part thereof) contains a defect or malfunction after a reasonable number of attempts by the warrantor to remedy defects or malfunctions in such product, such warrantor must permit the consumer to elect either a refund for, or replacement without charge of, such product or part (as the case may be).” 15 U.S.C. § 2304(a). The parties do not dispute that the warranty at issue here is “limited,” and, relevantly, it proscribes the recovery of consequential damages for a breach of the warranty terms. Because a limited warranty does not allow for recovery of damages beyond the cost of “repair/replace” for the defective product or part, the recovery under state breach of warranty claims is likewise limited. Because of this limitation, courts have construed the applicability of the MMWA and the availability of remedies thereunder.

*6 Specifically, in *Pyskaty*, the Second Circuit examined the MMWA’s jurisdictional requirement that the amount in controversy exceed \$50,000. 15 U.S.C.A. § 2310(d)(3)(B) (“No claim shall be cognizable in a suit brought under [the MMWA] ... if the amount in controversy is less than the sum or value of \$50,000 (exclusive of interests and costs) computed on the basis of all claims to be determined in this suit”). The district court held that the value of the state law warranty claims and the MMWA claims should not be aggregated in determining whether the plaintiff met the jurisdictional threshold. In determining whether plaintiff met this threshold, the Second Circuit examined the damages available under the MMWA:

Under section 2304 of the MMWA, when a warrantor breaches a “full” written warranty, the plaintiff is entitled to a refund or replacement without charge for the defective product. 15 U.S.C. § 2304(a)(4); see also *id.* § 2303(a)(1) (stating that a written warranty shall be designated as “full” where it “meets the Federal minimum standards for warranty set forth in section 2304”). However where, as here, the warrantor made only a “limited” written warranty, [record cite] (“Buyers Guide”) (designating the applicable warranty as a “limited warranty”); Appellant’s Br[ief] at 47 n.10 (acknowledging that *Pyskaty* is not seeking a “refund” under 15 U.S.C. § 2304), the text and legislative history of the Act indicate that “courts [should] look to state law to determine the applicable measure of damages, which informs the amount in controversy.”

Pyskaty, 856 F.3d at 223.

The MMWA distinguishes between “full” and “limited” warranties and, subject to certain exemptions, requires that written warranties be “clearly and conspicuously designate[d]” as one or the other. 15 U.S.C.

§ 2303(a). In order for a written warranty to qualify as a “full” warranty, the warrantor: (1) must agree to remedy the defective product within a reasonable time period and without charge; (2) may not impose any limitation on the duration of any implied warranty on the product; and (3) may not exclude or limit consequential damages for breach of any written or implied warranty on the product, unless such exclusion or limitation appears conspicuously on the face of the warranty. *Id.* § 2304(a)(1)-(3).

Id. at 223 n.12. Relevantly, under New York law, recovery under a limited express warranty is restricted to the difference between the product received and the product warranted. Contrary to Defendants' assertions, the Second Circuit did not hold that revocation is unavailable under New York law, but merely that the plaintiff could not seek a refund *under Section 2304 of the MMWA*. The Second Circuit so held because the parties agreed that the relevant warranty was limited and, thus, the remedies were available pursuant to state law rather than the MMWA. New York and Pennsylvania law are identical with respect to the revocation of acceptance due to nonconformity. *Compare* N.Y. U.C.C. Law § 2-608 with 13 Pa.C.S. § 2608.

In *Woolums*, the court addressed a factually similar claim where plaintiffs, who were purchasers of a different brand of recreation vehicle, repeatedly sought repairs at various authorized dealers, yet were unsatisfied with the repairs performed. The plaintiffs brought claims both under the UCC, as adopted by Pennsylvania, and the MMWA. Judge Conner denied the defendant's motion for summary judgment as to the MMWA claims and concluded that “a reasonable jury could find that defendants failed to abide by the terms of their warranty, in violation of the [MMWA].” *Woolums*, 530 F. Supp. 2d at 703. The court in *Woolums* did not unequivocally hold that revocation of the contract was unavailable, but merely that a factual issue arose over whether the vehicle had so “failed of its essential purpose” as to entitle plaintiffs to revocation under the UCC.

*7 A review of *Pyskaty* and *Woolums* demonstrates that there is no true conflict between New York and Pennsylvania law, nor are the two decisions incompatible. *Pyskaty* addressed only a jurisdictional question as to whether the amount in controversy was sufficient to support a claim under Section 2310(d)(3)(B) of the MMWA and concluded that, under a limited warranty, the court must look to the UCC to determine available remedies. In *Woolums*, the court concluded that the plaintiff could seek damages for the written warranty under the MMWA, which incorporates the underlying state law to determine damages under a limited warranty.⁴ In essence, both decisions stand for the proposition that the MMWA's expansive remedy scheme is applicable only to full warranties, but a plaintiff may still bring claims under the MMWA and seek remedies available under the relevant state law for breach of a limited warranty. It is uncontroverted that the remedies available under New York and Pennsylvania are the same. *Compare* NY UCC Law 2-714 with 13 Pa. C.S. § 2714 and *compare* N.Y. U.C.C. Law § 2-608 with 13 Pa.C.S. § 2608. Accordingly, the court finds that Defendants have failed to demonstrate a “true conflict” between the express warranty laws in Pennsylvania and New York. Thus, the law of the forum state, Pennsylvania, applies.

iii. Consumer Protection Laws

Defendant argues that New York Gen. Bus. Law § 349 (“Consumer Protection Law”) and the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201–1 *et seq.*, (“UTCPL”) conflict because the Consumer Protection Law requires “harm to the general public and not solely because of a contract.” In support of this argument, Defendant cites *Mahoney v. Endo Health*, No. 15-cv-9841, 2016 WL 3951185 (S.D.N. Y July 20, 2016). Plaintiff argues that Defendant misreads *Mahoney* to include the “general public” requirement and New York law requires only that a product be offered to the “general public”—i.e. consumers—to implicate the Consumer Protection Law.

In *Mahoney*, a plaintiff brought a putative class action against several companies involved with the manufacture and marketing of vitamin tablets. The defendants moved to dismiss, *inter alia*, the plaintiff's claims under the Consumer Protection Law. The *Mahoney* court set forth the elements of a valid cause of action under the Consumer Protection Law as follows:

To succeed on a § 349 claim, a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice. The New York Court of Appeals has adopted an objective definition of “misleading,” under which the alleged act must be likely to mislead a reasonable consumer acting reasonably under the circumstances. In addition, there must be a causal connection between the misrepresentation and some harm from, or failure of, the product.

Mahoney, 2016 WL 3951185 at *9 (internal citations omitted). Relevantly here, the court defined “consumer-oriented conduct” as follows:

Under New York law, conduct is “consumer-oriented” when it had a broader impact on consumers at large. Private contract disputes, unique to the parties, for example, would not fall within the ambit of the statute. This element thus may be satisfied by showing that the conduct at issue potentially affects similarly situated consumers. In sum, the injury must be to the public generally as distinguished from the plaintiff alone.

*8 *Mahoney*, 2016 WL 3951185 at *9 (citing *Euchner-USA, Inc. v. Hartford Cas. Ins. Co.*, 754 F.3d 136, 143 (2d Cir. 2014) (“deceptive conduct aimed at the public at large” is consumer-oriented) (citation omitted)).

Based on this language and the cases cited in *Mahoney*, the court agrees with Plaintiffs' reading of the “consumer-oriented conduct” requirement under New York Law. Simply, the Consumer Production Law creates a distinction between public facing products that are sold to consumers and “private contract disputes” such as specialized or unique products sold pursuant to a private agreement. For example, a custom piece of medical equipment created for a research hospital would not be “consumer-oriented” in the same sense as a diabetic's insulin monitor. The *Mahoney* court itself actually expounds on this distinction and rejects the defendants' argument that the vitamin tablets were not consumer-oriented:

The defendants contend that the statements at issue were directed to doctors or pharmacists, not patients, and therefore the statements were not meant to mislead consumers. The cases the defendants cite in support of their argument involve large private transactions between sophisticated businesses and therefore do not address the facts at hand. [See e.g., *Weiss v. Polymer Plastics Corp.*, 802 N.Y.S.2d 174, 176 (2d Dep't 2005) (“The transaction in this case was between two companies in the building and supply industry.”); *St. Patrick's Home for Aged & Infirm v. Laticrete Int'l, Inc.*, 696 N.Y.S.2d 117, 122 (1st Dep't 1999) (“The transaction in this case was a sizable one between two companies ... this was not the type of ‘modest’ transaction that the statute was intended to reach.” (citation omitted)).

Mahoney, 2016 WL 3591185 at *9-10. In *Weiss*, the New York Appellate Division Second held that the sale of an exterior coating for home construction from a plastic manufacturer to a general contractor was not “consumer oriented” because the synthetic plastic company had no dealings with home buyers. *Weiss*, 802 N.Y.S. 2d at 176. In *St. Patrick's*, a premade wall panel manufacturer sold wall panels to a third-party installer, apparently after consultation with the architect and general contractor, but had no contact with the plaintiffs. *St. Patrick's Home for Aged & Infirm*, 696 N.Y.S. 2d at 120. The court found that the defendants' conduct was not consumer oriented because it dealt only with “sophisticated business entities ... act[ing] in an intermediary role in the transaction, thereby reducing any potential that a customer in an inferior bargaining position would be deceived.” *Id.* at 122 (“In short, this was not the type of “modest” transaction that the statute was intended to reach”); see also *Genesco Entertainment v. Koch*, 593 F. Supp. 743, 752 (S.D.N.Y. 1985) (holding that a negotiation for rental of Shea Stadium was a “single shot transaction”, not a typical consumer transaction and therefore not covered by section 349). The UTPCPL

achieves a similar result albeit by different means. Pennsylvania courts and the Third Circuit have held that parties who made the relevant purchase or lease for business or commercial purposes may not assert a UTPCPL claim. *New Legion Co., Inc. v. Thandi*, No. 18-cv-778, 2018 WL 2121523, at *5 (E.D. Pa. May 8, 2018) (citing *Balderston v. Medtronic Sofamor Danek, Inc.*, 285 F.3d 238, 242 (3d Cir. 2002) (doctor could not assert UTPCPL deceptive marketing claim for bone screws he had bought for his professional practice); *Trackers Raceway, Inc. v. Comstock Agency, Inc.*, 583 A.2d 1193, 1197 (Pa. Super. Ct. 1990) (plaintiff failed to state UTPCPL claim where it purchased an insurance policy “for commercial purposes only”)). Because both laws require the product at issue be offered to the public for consumer use, there is no actual conflict between the UTPCPL and the Consumer Protection Law. Accordingly, the law of the forum applies here and the court will analyze Plaintiffs’ consumer protection claims under the UTPCPL.

B. Breach of Warranty

*9 Having concluded that New York law applies to Plaintiffs’ implied warranty claims, and Pennsylvania law applies to Plaintiffs’ express warranty and consumer protection law claims, the court will now address Defendant’s argument that Plaintiffs’ express warranty claim fails because Plaintiffs voided the warranty. The written warranty provides, in pertinent part:

This New Vehicle Limited Warranty (“NVLW”) is the sole and exclusive warranty applicable to this Winnebago or Itasca motor home made or authorized by Winnebago Industries, Inc. (“Winnebago”) and provides coverage so long as the motor home is used exclusively for recreational purposes in the U.S.A. or Canada.

(Doc. 81, Ex. 6.) The warranty also excludes from coverage “a motor home used for a purpose other than recreational use,” although it does not define the term “recreational use.” *Id.* Defendants argue that the Plaintiffs intended to use the RV as a permanent residence and that doing so goes beyond the scope of “recreational use.” Plaintiffs do not argue that actual use of the RV as a permanent residence would go beyond “recreational use;” instead, they argue that their actual use of the RV over the approximately 12 months they owned it still constitutes “recreational use” and their subjective intent to use the RV as a residence at a future date is irrelevant.

Under Pennsylvania law, a contract is ambiguous when “it is reasonably or fairly susceptible of different constructions and is capable of being understood in more senses than one and is obscure in meaning through indefiniteness of expression or has a double meaning.” *Duquesne Light Co. v. Westinghouse Elec. Corp.*, 66 F.3d 604, 614 (3d Cir. 1995) (quoting *Samuel Rappaport Family P’ship v. Meridian Bank*, 657 A.2d 17, 21-22 (1995)). If a court determines that a contract is ambiguous, then “a decision as to which of the competing interpretations of the contract is the correct one is reserved for the factfinder, who would examine the content of the extrinsic evidence (along with all the other evidence) in order to make this determination.” *Phila. Workforce Dev. Corp. v. KRA Corp.*, 673 F. App’x 183, 188 (3d Cir. 2016) (citing *Bohler–Uddeholm Am., Inc. v. Ellwood Grp., Inc.*, 247 F.3d 79, 94 (3d Cir. 2001)). Initially, the court must determine if the term “recreational use” is capable of being understood in more than one sense.

The warranty itself does not define recreational use, and it does not limit the duration of recreational use or the length of a single trip. Plaintiffs have submitted advertisements by Defendant that markets the RV for “extended stays” and for use for an unquantified number of days in a year. (See Doc. 81, Ex. 2, “Winnebago Four Simple Questions Brochure,” at p. 2 (the “Brochure”).) According to the Brochure, Defendant’s vehicles offer several features that imply that the purpose of the RV is to make extended trips using the RV as a mobile residence: up to 160 cubic feet in exterior storage, a kitchen pantry, kitchen cabinets, appliances, and household amenities such as bedrooms with closets and king sized beds, bathrooms with large showers and double vanities, a fireplace, a full kitchen, sofas and chairs, a dining table, and other features. The brochure provides that the vehicles are tested to withstand 40,000 miles per week, and that Defendant has 200 authorized dealers nationwide who are

certified to repair and service the vehicles. Plaintiffs additionally cite to an advertisement by Defendant involving a family who made a 10-month extended trip across the United States in their RV. (*Id.* at Ex. 6.) Defendants have presented no evidence that would indicate that the term “recreational use” in the context of the RV does not extend to a months-long trip across the country, and the marketing materials and design of the RV indicate that its purpose was for extended habitation while travelling. Thus, the context of the term “recreational use” implies that it encompasses long distance travel and extended periods of time where the owners use the RV as a mobile residence. What is unclear, however, is whether Plaintiff's stay was so lengthy that it exceeded the intended use of the RV.

*10 Plaintiffs' assert that they intended to take an initial extended 12-month trip across the country with their dogs. (Doc. 82, Ex. 2, ¶ 3.) Prior to departing on their extended trip, they sold their house, Ms. Hanreck quit her job, and they established residency in Florida. Aff. H. Hanreck (Exhibit 2). They camped and travelled while they were allegedly in the search of a new “home base.” *Id.* None of the facts presented show that the Plaintiffs clearly exceeded the bounds of the warranty definition of “recreational use.” On the one hand, Plaintiffs had no other permanent residence; yet Plaintiffs have plausibly asserted that they chose the timing of this trip specifically because they intended to seek an alternative domicile and were attempting to avoid paying for a house that they would not reside in while they travelled the country. Plaintiffs' trip extended for approximately 12 months,⁵ but there is no indication that Defendant's warranty placed any express temporal limits on travel and a 12-month trip is not obviously longer than the RV's intended purpose. Defendant in fact appears to have expressly endorsed trips lasting up to 10 months. Of course, if the Plaintiffs had been on the road for two or three years, it would be easier to conclude that they had little intention to “put down roots,” yet their conduct here falls into a grey area between recreational and residential use. Lacking a factual basis to establish that Plaintiffs use of the RV extended beyond recreation use, Defendant's place great weight on their representations of subjective intent to do so. Thus, the court will examine Plaintiffs' initial representations that they intended to use the RV as a permanent residence.

Defendants cite to two statements made by Plaintiffs: (1) Ms. Hanreck's statement that she understood that “recreational use” did not include use of the RV as a primary residence; and (2) her statement that they did intend to use the RV as a permanent residence. (*See* Doc. 81, Ex. C, p. 24.) Under Defendant's construction of the warranty, a purchaser could void the warranty the day of purchase by simply stating the words “this vehicle is now my place of residence.” (*See* Doc. 30, p. 10) (“As the Plaintiffs admittedly used the [RV] as their primary residence, and not exclusively for recreational use as early as May 20, 2015 [less than one month after receipt of the RV], there cannot be any warranty contract-based dispute as a matter of law.”) Such an interpretation is certainly not the definitive interpretation of the warranty language and is not apparent from the contract itself or any extrinsic evidence presented. Although the Plaintiffs may have stated that they had considered using the RV as their residence and understood that using the RV as a permanent residence exceeded the terms of the warranty, there is no factual support that their actual usage of the RV extended beyond its intended use as a recreational vehicle. At minimum, this raises a factual issue as to whether the Plaintiffs use of the RV to travel the United States for approximately 10-12 months exceeded its intended use as a recreational vehicle. Accordingly, the court finds that the warranty language is ambiguous and there is a factual issue as to whether Plaintiffs conduct exceed the bounds of “recreational use.”

C. Magnuson Moss Warranty Act Claims

Defendant next argues that the MMWA is inapplicable to the claims raised under either the express or implied warranties. As discussed in part above, the MMWA does not create a new claim, but provides additional federal remedies for certain types of warranties. Defendant cites numerous cases from jurisdictions other than Pennsylvania or New York. A close reading of the cases cited by Defendant shows that none of those courts actually dismissed the MMWA claims because the warranties were “limited” as Defendant argues. A more accurate statement of those holdings is that the courts held that a plaintiff cannot recover more damages under the MMWA than he or she could under the applicable state law warranty claims if the warranty does not meet the criteria for a “full” warranty under the MMWA. *See In re Rust-Oleum Restore Mktg., Sales Practices & Prod. Liab. Litig.*, 155 F. Supp. 3d 772, 797 (N.D. Ill. 2016) (explaining that “the MMWA allows consumers to enforce limited written and implied warranties in federal court, as provided in [section 2310\(d\)\(1\)](#), borrowing state law causes of action” (internal quotations

and alternations omitted)); see also *Milicevic v. Fletcher Jones Imports, Ltd.*, 402 F.3d 912, 918 (9th Cir. 2005). (“Thus, it is clear from the statutory language that the [MMWA] creates a private cause of action for a warrantor's failure to comply with the terms of a written warranty, and none of the cases cited by [the defendants] support a contrary position. Finally, in this regard, whether the written warranty is full or limited makes no difference. Although the [MMWA] distinguishes between full and limited warranties, it nonetheless refers to each as a written warranty. 15 U.S.C. § 2303(a)(1)-(2).”). This court agrees with the interpretation expressly made by the Ninth Circuit and implied in each other case cited by the parties: that the MMWA supports a claim arising from both limited and full warranties, but applies its expansive remedial scheme only to full warranties.

*11 Plaintiffs, in their brief in opposition to summary judgment, go beyond the arguments raised by Defendant. Plaintiffs suggest that the MMWA provides for “equitable relief” that can include rescission of the contract. Although some courts have agreed with this position, it is unsettled, particularly within Pennsylvania and the Third Circuit. Even in jurisdictions where courts have allowed such an equitable remedy, other courts have questioned this approach. Compare *Jones v. Fleetwood Motor Homes*, No. 98 C 3061, 1999 WL 999784 (N.D. Ill. October 29, 1999) and *Hamdan v. Land Rover N. Am., Inc.*, No. 03-cv-2051, 2003 WL 21911244 (N.D. Ill. August 8, 2003) with *Mydlach v. DaimlerChrysler Corp.*, 875 N.E.2d 1047, 1064 (Ill. 2007) (“We remain unpersuaded, however, that simply because the [MMWA] allows an action for equitable relief, revocation must be available for all breaches of warranty, irrespective of the status of the defendant or the relationship between the parties. Rather, we agree ... that revocation of acceptance is “conceptually inapplicable” to a nonseller.”); see also 12 Reasons to Love the Magnuson-Moss Warranty Act, 11 J. Consumer & Com. L. 127, 130 (2008) (comparing *Hamdan* with *Stoebner Motors, Inc. v. Automobili Lamborghini S.P.A.*, 459 F. Supp. 2d 1028 (D. Haw. 2006) (revocation not available against remote manufacturer without privity) and *Chaurasia v. Gen. Motors Corp.*, 126 P.3d 165 (Ariz. Ct. App. 2006) ([MMWA]’s authorization of equitable relief does not, in the absence of privity, allow consumer to revoke acceptance against manufacturer)). Other courts have expressly held that under the MMWA, the remedy of recession applies only to full warranties. *Id.* (citing *Holmes v. Kabco Builders, Inc.*, 62 U.C.C. Rep. Serv. 2d 239, 244 n.7 (S.D. Ala. 2007); *Traynor v. Winnebago Indus., Inc.*, 2006 WL 778703 (D. Ariz. Mar. 27, 2006)); *Long v. Monaco Coach Corp.*, No. 04-cv-203, 2006 WL 2564040, *5 (E.D. Tenn. Aug. 31, 2006) (“because the warranty in issue is not a “full” warranty but a “limited” warranty and because there is no privity of contract between the [parties], the [plaintiffs]’ request for revocation of acceptance relief is not a remedy available to them under the MMWA.”).

Plainly stated, Section 2304 of the MMWA applies only to written, full warranties and expressly allows for “a refund or replacement without charge,” while Section 2310 applies to all “written warranties,” but only provides that a consumer “may bring suit for damages and other legal and equitable relief.” Consistent with other holdings concluding that, where the MMWA is silent, state warranty law applies,⁶ this court concludes that the reference to “damages and other legal and equitable relief” means those damages and equitable remedies that would be available under the applicable state law. Defendants have cited no authority that would preclude a refund or replacement of the RV, but neither Plaintiffs nor the court have found a case in Pennsylvania that granted the remedy of revocation or recession based on a manufacturer's warranty. See Curtis R. Reitz, *Manufacturers' Warranties of Consumer Goods*, 75 Wash. U. L.Q. 357, 396 (1997) (“It is incoherent to use “revocation of acceptance” in connection with remedies for breach of a manufacturer's warranty to a remote buyer. Without regard to acceptance and revocation of acceptance, however, there may well be breaches of manufacturers' warranties that, under common-law remedial principles, justify a measure of damages that includes the full amount of the retail price paid.”). It appears that, in this context, “equitable relief” may encompass refund or reimbursement rather than “revocation or recession” because the dealer that sold the RV is not a party to this action. Thus, it remains a question for the jury as to whether Defendant's alleged delay in repairing the RV so “failed its essential purpose” as to justify equitable relief in the form of refund or replacement under the UCC, see *Woolums*, 530 F. Supp. 2d at 701 (“Whether a limited warranty has failed its essential purpose is a question of fact for the jury.”), but it does not appear that revocation or recession of the sale would be available in this case.

D. State Law Warranty Claims

i. Express Warranty

*12 Plaintiffs argue that Defendant breached the express warranty given to them at the time they purchased the RV. Under Pennsylvania law, in order to prove breach of an express warranty, a plaintiff must show that an express warranty existed, that a breach of the warranty occurred, and that the breach was the proximate cause of the specific damages. *Giacalone v. Lacrimedics, Inc.*, No. 07-cv-2212, 2008 WL 11365183, *6 (E.D. Pa. Nov. 24, 2008) (citing *Price v. Chevrolet Motor Div. of Gen. Motors Corp.*, 765 A.2d 800, 809 (Pa. Super. Ct. 2000)). Here, the parties do not dispute that an express warranty existed. Defendant, however, argues that the terms of the contract excluded the damages Plaintiffs seek or that Plaintiffs voided their warranty by failing to conform to the terms of the warranty.

In pertinent part, the warranty provides: “[Defendant] promises that any part of this motor home ... found to be defective in material or workmanship shall be repaired or replaced at no cost to the owner for parts, material, or labor so long as the motor home has been used exclusively for recreational purposes and maintained as recommended.” (Doc. 37, Ex. C, p. 160.) The warranty prescribes a specific method of obtaining repairs or replacements: “to obtain warranty repairs, you must, at your own cost, present your motor home to an authorized [Defendant] service facility during normal business hours and provide a written list of items to be inspected or repaired to the service facility and [Defendant].” (*Id.*) The warranty also requires that, if a service facility is unable to satisfactorily perform the repairs, the owner must present the motor home to one of Defendant's factories for repair directly by Defendant. Additionally, the warranty contains a limitation on remedies clause which, in essence, limits the amount a plaintiff can recover for a breach of the warranty to “money damages in an amount equal to the reasonable cost for material and labor necessary to repair or replace parts that should have been done under th[e Warranty], but were not.” (Doc. 37, Ex. C.)

The parties do not dispute the facial validity of the limitation of damages provision or that Plaintiffs failed to follow the required procedure for factory repairs in April of 2016 when they cancelled their scheduled repair at Defendant's factory. (See Doc. 38, Ex. M; Ex. C, p. 98.) Instead, Plaintiffs argue that, because of the numerous and repeated repairs needed during their year-long trip, the warranty failed of its essential purpose such that the limitation provision is invalidated under Pennsylvania law. See *Woolums*, 530 F. Supp. 2d at 700-701 (citing *Strickler*, 2005 WL 1266674, at *4); see also *Hornberger v. Gen. Motors Corp.*, 929 F. Supp. 884, 890 (E.D. Pa. 1996) (finding that a buyer may “pursue remedies under the [UCC] where the exclusive remedy provided in the contract ‘fails of its essential purpose.’ ”) (citing 13 Pa.C.S. § 2719(b)). “A remedy fails of its essential purpose where it deprives either party of the substantial value of the bargain.” *Earl Brace & Sons v. Ciba-Geigy Corp.*, 708 F. Supp. 708, 710 (W.D. Pa. 1989).⁷

*13 Plaintiffs cite to a laundry list of repairs that were performed at various service centers over the course of their travels in the RV: auto shade malfunctions, battery charging issue, drivers side slide seal, generator, shade wires, hall monitor light, slide operation, entertainment system not working, shower leak, inverter not working, rust under camper, “auto jack” light broken, battery latch, backup camera, installed satellite, chassis and house battery wiring, stove burner not working, tow kit installation, steps not retracting, slide topper ripped and worn, corroded water pump, brakes skipping and smoking, engine squeaking, chair adjustment broken, cap on bedroom slide, dinette slide creaking, tank sensors stuck, foot rest broken, light fixture flickers, heat and AC, outside TV and “video transfer box” not working, blue ox tow kit breaks, water leak, and transfer box. (Doc. 81, Ex. 2; 10-20.) At least some of these issues were not fully repaired or, according to Plaintiffs' expert witness, were not repaired within a reasonable period of time. (Doc. 81, Exs. 1, 2.) Plaintiffs argue that the total number of repairs, the repairs that failed to correct the issues, and the unreasonable amount of time it took to make the repairs that were completed amounts to a breach of the express warranty.

In *Woolums*, the court denied summary judgment on a similar issue, finding that certain defects that the plaintiffs presented to National RV for repair were rejected or incorrectly repaired and that, taken together, the numerous recurring failures and needs for repair raised an issue of fact as to whether the totality of the equipment failures constituted a failure of the warranty's essential purpose. Attempting to distinguish *Woolums*, Defendant cites *Pidcock v. Ewing*, 435 F. Supp. 2d 657 (E.D. Mich.

2006) for the proposition that “[t]he fact that the motor home was previously serviced is not enough to establish a breach of [an] express warranty.” *Pidcock*, 435 F. Supp. 2d at 663 (citing *Ducharme v. A & S RV Ctr.*, 321 F. Supp. 2d 843, 850-51 (E.D. Mich. 2004) (observing that (1) “the fact that the motor home was previously repaired does not establish a breach of an express warranty”, (2) some service on a complex product like a motor home is inevitable, and (3) there is no breach when the manufacturer is willing to repair an existing problem under the warranty), *aff’d*, 127 Fed. App’x 204 (6th Cir. 2005)). Both *Pidcock* and *Ducharme*, however, apply Michigan case law that prohibits an aggregation of repair time over the lifetime of the warranty. See *Pidcock*, 435 F. Supp. 2d at 663 (citing *Comput. Network, Inc. v. AM Gen. Corp.*, 696 N.W. 2d 49, 55 (Mich. App. 2005) (“There were numerous different repairs to the vehicle over a lengthy period, most of which were not repeat repairs. Plaintiff relies on the aggregate number of repair days to argue that there is a question of fact whether the time for repairs was unreasonable. However, it offers no evidence that the time to perform the numerous, individual repairs was unreasonable for this specific vehicle.”)). Initially, the instant case is distinguishable from the Michigan cases because there is evidence of the need for repeat repairs for the same issue. Moreover, Defendant cites no Pennsylvania case law that supports the theory that a plaintiff is prohibited from aggregating time that the vehicle was out of service over the life of the warranty. In fact, this appears to be the exact reasoning relied upon by the *Woolums* court in finding an issue of fact arose as to whether the warranty failed of its essential purpose. Although the Pennsylvania Lemon Law is inapplicable here—motor homes are expressly excluded, 73 P.S. § 1952—the Lemon Law provides that a manufacturer shall be given a reasonable number of attempts to repair defects and presumes that a reasonable number of attempts shall not exceed 30 calendar days. 73 P.S. § 1956. The RV appears to have been in the shop for repairs approximately 31 days, not including the time between purchase and initial delivery or after Plaintiffs declined the factory repair.

Defendant does not argue that any of the repairs were not covered by the warranty and, as noted above, there are several repairs that may have been inadequately performed over the lifetime of the warranty. Because the number of attempted repairs and the continued need for repeated repairs of the same issue, the court finds that Plaintiffs have raised a genuine issue of material fact as to whether the total number of repairs constitutes a breach of the express warranty and a failure of its essential purpose. Accordingly, Defendant's motion for summary judgment as to the express warranty claim will be denied.

ii. Implied Warranty

*14 Plaintiffs claim that Defendant breached its implied warranty of merchantability because the RV was unfit for its intended purpose and required repeated repairs. As noted above, the Pennsylvania Supreme Court has abolished the requirement that the plaintiff be in privity of contract with the manufacturer in order to bring a claim. *Hull v. Fleetwood Enters., Inc.*, No. 06-cv-1669, 2007 WL 917088, *3 (W.D. Pa. Mar. 21, 2007), *on reh’g*, No. 06-cv-1669, 2008 WL 519608 (W.D. Pa. Feb. 25, 2008) (citing *Goodman v. PPG Indus.*, 849 A.2d 1239 (Pa. Super. Ct. 2004)). However, because New York law applies to Plaintiffs' implied warranty claim and it is uncontested that New York still holds fast to the requirement of privity in implied warranty cases, there is little question that Plaintiffs' implied warranty claims should be dismissed. *Haag v. Hyundai Motor Am.*, 969 F. Supp. 2d 313 (W.D. N.Y. 2013); *Lexow & Jenkins, P.C. v. Hertz Comm. Leasing Corp.*, 122 A.D. 2d 25, 26 (N.Y. App. Div. 1986). Because Plaintiffs purchased the RV from a third-party seller, they lack privity with Defendant and, thus, summary judgment is proper as to their implied warranty claim under state law and the MMWA.

E. Consumer Protection Laws

Plaintiffs plead alternatively under both the New York Consumer Protection Law and Pennsylvania's UTPCPL, 73 Pa. C.S. § 201 *et seq.* Because Pennsylvania law applies, the court need only address Defendant's argument that Plaintiff fails to prove all the required elements of a claim under the UTPCPL. The UTPCPL grants a private right of action to consumers harmed by deceptive business practices. 73 Pa. C.S. § 201-9.2(a). The purpose of the UTPCPL is to deter “unfair and deceptive business practices.” *Commonwealth v. Monumental Props.*, 329 A.2d 812, 815-17 (Pa. 1974). The statute's “underlying foundation is

fraud prevention,” and its strategy is to place the consumer and the seller on more equal terms. *Id.* at 816. Because the law is remedial in nature, courts should construe its provisions liberally. *Id.* at 816-17.

In order to maintain a private right of action under the UTPCPL, Plaintiffs must demonstrate that they:

1) purchased or leased goods or services primarily for a personal, family, or household purpose; 2) suffered an ascertainable loss of money or property; and 3) the loss occurred as a result of the use or employment by a person of a method, act, or practice declared unlawful by the UTPCPL. 73 P.S. § 201-9.2(a). The plaintiff must offer evidence of one of the statutorily delineated “unfair methods of competition” found at 73 P.S. § 201-2(4), or evidence which fits the “catch-all provision” found at 73 P.S. § 201-2(4)(xxi).

Baynes v. George E. Mason Funeral Home, Inc., No. 09-cv-153, 2011 WL 2181469, *4 (W.D. Pa. June 2, 2011).⁸

Plaintiffs allege that Defendant violated the UTPCPL by committing the following “[u]nfair methods of competition” and “unfair or deceptive acts or practices”:

(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;

...

(vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

*15 ...

(ix) Advertising goods or services with intent not to sell them as advertised;

...

(xiv) Failing to comply with the terms of any written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made;

...

(xvi) Making repairs, improvements or replacements on tangible, real or personal property, of a nature or quality inferior to or below the standard of that agreed to in writing;

...

(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

73 P.S. § 201-2(4). Plaintiffs first argue that a breach of written warranty can be an unfair or deceptive act under the UTPCPL. See *Woolums*, 530 F. Supp. 2d at 703 (citing § 201-2(4)(xiv); see also *Keller v. Volkswagen of Am., Inc.*, 733 A.2d 642, 647 (Pa. Super. 1999) (reversing trial court's grant of summary judgment to defendant automobile manufacturer on plaintiff's UTPCPL claim for breach of repair-or-replace warranty because plaintiff repeatedly returned vehicle for the same recurring problem)). Plaintiffs also allege that Defendant misrepresented the quality, characteristics, and capabilities of the RV, which led to confusion and misunderstanding, and induced Plaintiffs to purchase the RV.

i. Economic Loss Doctrine

Rather than raising challenges to Plaintiffs' claims that Defendant's conduct violated the UTPCPL, Defendant argues that Plaintiffs are precluded from recovery under the UTPCPL by the economic loss doctrine. In short, the economic loss doctrine bars a plaintiff from recovering tort damages for economic losses stemming solely from a breach of contract. See *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 671 (3d Cir. 2002). It prohibits claims “(1) arising solely from a contract between the parties; (2) where the duties allegedly breached were created and grounded in the contract itself; (3) where the liability stems from a contract; or (4) where the tort claim essentially duplicates a breach of contract claim or the success of which is wholly dependent on the terms of a contract.” *McGuckin v. Allstate Fire & Cas. Ins. Co.*, 118 F.Supp.3d 716, 720 (E.D. Pa. 2015) (internal quotations omitted). Defendant argues that Plaintiffs' claims must fail because they seek only to recover the lost benefit of their bargain under the contract for sale and the Warranty. (Doc. 28, p. 26-27) (citing *Dusquesne Light Co. v. Westinghouse Elec. Corp.*, 66 F. 3d 604, 618 (3d Cir. 1995).)

The applicability of the economic loss doctrine in the Third Circuit has been a hotly debated question in the last several years. Initially, in *Werwinski*, the Third Circuit predicted that the Pennsylvania Supreme Court would conclude that UTPCPL claims would be barred by the economic loss doctrine, comparing such claims to the “gist of the action” doctrine applied in Pennsylvania Courts. The Third Circuit's prediction, however, was contradicted by the Pennsylvania Superior Court on two separate occasions. See *Dixon v. Nw. Mut.*, 146 A.3d 780, 790 (Pa. Super. Ct. 2016); *Knight v. Springfield Hyundai*, 81 A.3d 940, 952 (Pa. Super. Ct. 2013). Since then, over a dozen decisions by various district courts throughout the Third Circuit have reached contradictory holdings over whether *Werwinski* remains controlling. See *McDonough v. State Farm Fire & Cas. Co.*, 18-cv-02247, 2019 WL 480139, *5 (E.D. Pa. Feb. 7, 2019) (collecting cases). “Courts within the Third Circuit are bound by previous holdings of the Circuit on matters of state law, absent ‘a clear statement by the Pennsylvania Supreme Court to the contrary or other persuasive evidence of a change in Pennsylvania law.’ ” *Powell v. Saint Joseph's Univ.*, 17-cv-4438, 2018 WL 994478, *9 (E.D. Pa. Feb. 20, 2018) (quoting *Smith v. Calgon Carbon Corp.*, 917 F.2d 1338, 1343 (3d Cir. 1990) (emphasis in original)) (citing *Debiec v. Cabot Corp.*, 352 F.3d 117, 131 (3d Cir. 2003) (ruling that a previous holding by the Circuit is “binding ... notwithstanding the contradictory Pennsylvania Superior Court opinions on th[e] issue”)). Although *Powell* concluded that *Knight*, standing alone, did not amount to “persuasive evidence of a change in Pennsylvania law,” it does not appear to have considered *Dixon*, which follows *Knight* and recognizes the contradiction between substantive law applied in state and federal courts on this issue. *Dixon v. Nw. Mut.*, 146 A.3d at 790 n.12. Although this court agrees with *Powell* that the Court in *Knight* did not perform an in-depth analysis of the law, this court is not tasked with critiquing the thoroughness of an intermediate state court's decision-making. Instead, it appears that *Knight* is the controlling state law on this issue and has been for approximately six years. It has not been contravened or questioned by any subsequent holding of another intermediate panel or *en banc* sitting of the Superior Court and has been followed as the law of the land in Pennsylvania. The court finds that this is sufficiently persuasive of a change in the law. Accordingly, Defendant's argument that the economic loss doctrine bars Plaintiff's claims is unavailing.⁹

ii. UTPCPL Claim

*16 Having concluded that Plaintiffs' claims are not barred by the economic loss doctrine, the court will examine the substantive allegations of violations under the UTPCPL. Plaintiffs argue that the following conduct constitutes unfair or deceptive trade practices:

Defendant represented that the vehicle had performance, characteristics, accessories, uses, or benefits it did not have; Defendant represented the vehicle as a particular standard of quality or grade when it was not; Defendant represented it was able to deliver or complete the transaction when it knew it could not, represented the defects were repaired when they were not; solicited Plaintiffs to enter into oppressively

harsh or one-sided contract and made false and misleading advertising, all address misrepresentation and/or false advertising.

(Doc. 81, p. 36 (citing Doc. 1, ¶ 39).) Essentially, it appears that Plaintiffs state that Defendant represented that the RV was in approximately new condition and was suitable for a long-term trip across the United States, when, in fact, the RV was sold to Plaintiffs with numerous defects and inadequacies that caused them to seek repeated repairs and that the RV was not capable of sustaining an approximately year-long trip as represented. Furthermore, Plaintiffs note that the repeated repairs were inadequate where Defendant had promised that they would correct the problems raised by Plaintiffs. The expert reports presented by Plaintiffs support their argument that the RV was not up to the promised quality, and the emails from Defendant's representatives at least support a conclusion that Defendant promised to rectify these mistakes, yet fell short of that promise. This claim dovetails with Defendant's argument that Plaintiffs voided the warranty by using the RV beyond "recreational use." As with that argument, whether Defendants represented that the RV was capable of performing a trip of this length and whether Plaintiffs exceeded "recreational use" by embarking on such a trip is a question for the jury. Defendant raises no argument to contradict the substantive claims raised by Plaintiffs and the court finds that they have raised legitimate issues of fact as to whether Defendant violated the UTPCPL. Accordingly, the court will deny Defendant's motion for summary judgment as to Plaintiffs claims under the UTPCPL.

IV. Motions in Limine

A. Cross-Motions Regarding Admission of Felony Conviction

Plaintiffs have retained Thomas Bailey ("Bailey") as an expert witness in this matter and he and he has rendered opinions on both the RV's defects and its value. (Doc. 40, Exs. A, B.) During the course of deposing Bailey, Defendant learned that he had previously been convicted of felony crimes. (*Id.* at 5, (citing Doc. 39, Ex. E, p. 112-113).) Defendant does not present direct evidence of Bailey's conviction, but instead cites to testimony Bailey gave in an unrelated case wherein he stated that he was convicted of a felony involving ten counts of mail fraud and perjury/misrepresentation to a Grand Jury. Bailey stated that he was convicted in 1994 and served a term of approximately 38-40 months. He further stated that he was not "in the RV business" from 1990-1994. While being deposed in the instant case, Bailey testified that he did not recall the exact crimes that he had previously been convicted of. Plaintiffs shed more light on Bailey's past conviction, stating that, between 1986 and 1990, he was the owner and operator of a federally licensed firearms dealer for law enforcement. (Doc. 52, p. 2.) Plaintiffs argue that the convictions should be excluded under the general rule that convictions over 10 years old should be inadmissible because Bailey's prior convictions have no relation to the instant case and his reliability as a witness has not been questioned in the nearly 25 years since his convictions.¹⁰

*17 Defendant concedes that [Federal Rule of Evidence 609\(b\)](#) typically excludes evidence of felony convictions more than 10 years old, but argues that "the probative value of the conviction supported by specific facts and circumstances substantially outweighs its prejudicial effect," and, thus, justifies admission of the convictions in this case. Under [Rule 609](#), which governs the use of convictions as evidence of truthfulness for impeachment purposes, a conviction more than 10 years old may not be admitted unless "its probative value, supported by specific facts and circumstances, substantially outweighs its prejudicial effect." [Fed. R. Evid. 609\(b\)\(1\)](#); *United States v. Shannon*, 766 F.3d 346, 352 n.9 (3d Cir. 2014). "The Advisory Committee Notes for [Rule 609\(b\)](#) emphasize that convictions over 10 years old will be admitted very rarely and only in exceptional circumstances." *Id.* (citation omitted). Applying this standard, Defendant has adduced no "exceptional circumstances" that would justify deviating from the general rule in this case. The only support for its position offered by Defendant is Bailey's alleged "evasiveness" when asked about his prior convictions. Bailey did not lie about his convictions or refuse to answer questions about them. Instead, he merely stated that he could not remember the specific crimes, but that they were related to "firearms violations." Although that is an incomplete summary of the charges, it is not so disingenuous as to amount to the exceptional circumstances necessary to justify admission of stale offenses. In contrast, Plaintiffs cite to the general age of the

convictions, the fact that the crimes were unrelated to Bailey's current occupation, and evidence of his rehabilitation such as letters of commendation for his efforts in assisting police in fraud investigations. (*See, e.g.*, Doc. 51-3.) Accordingly, the court finds that Defendant has failed to adduce evidence that would overcome Rule 609's preclusion of convictions more than ten years old and will grant Plaintiffs' motion *in limine* to exclude evidence of Bailey's convictions.

B. Cross Motions to Preclude Expert Testimony

i. Defendant's Challenge to Plaintiffs' Expert

Defendant presents a motion to preclude Bailey's testimony entirely because he fails to meet the criteria for admission as an expert witness. The admissibility of expert testimony is governed, in part, by Federal Rule of Evidence 702, which provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case.

The District Court has broad discretion in determining the admissibility of particular expert testimony. *See Walker v. Gordon*, 46 F. App'x 691, 694 (3d Cir. 2002) (citing *Kumho Tire v. Carmichael*, 526 U.S. 137, 152-53 (1999)). The Third Circuit has set forth three criteria to determine whether a proposed witness may qualify as an expert: qualification, reliability, and fit. *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003). Doubts about admissibility should be resolved in favor of admission. *Giorgini v. Ford Motor Co.*, No. 06-cv-968, 2008 WL 859230, *5 (E.D. Pa. Mar. 28, 2008).

Defendant raises the following challenges to Bailey's qualifications: (1) he has not had any classroom education or training on defect investigation or appraisal; (2) he has not relied on any industry writing, publication, or treatise on the issues raised; (3) he has no particular training on the specific product at issue here; and (4) his opinions are largely based on his own experience rather than formal training. Defendant's attacks on Bailey's qualifications are unpersuasive. Although Plaintiffs admit that he largely has little formal training, there is no stringent requirement that all expert knowledge must be obtained through formal training. Indeed, Plaintiffs cite to Bailey's decades of personal experience purchasing, selling, and inspecting RVs. (Doc. 61, Exs. 1A, 4.) Defendant does not direct this court to any authoritative publications that Bailey should have relied upon and, in fact, it appears that Defendants' own expert similarly rests his opinion predominantly on personal experience rather than formal publications. Accordingly, the court finds that Bailey meets the "qualifications" prong of the *Schneider* test.

Defendant additionally attacks Bailey's reliability as an expert, arguing that his methods and procedures are based on "subjective belief or unsupported speculation," rather than "the methods and procedures of science." *In re Paoli R.R. Yard PCB Litig*, 35 F.3d 717, 742 (3d Cir. 1994). Bailey, however, outlines his inspection and valuation methodology in his reports. (*See, e.g.*, Doc. 62, Exs. 1C, 1D.)¹¹ Obviously, a portion of the methodology is subjective to the extent that it is based on Bailey's personal observations; however, this criterion is part and parcel of the qualifications factor; Bailey's prior experience in the industry qualifies him to make such visual assessments. Other courts, cited by Plaintiffs, have expressly approved of visual inspections used to identify mechanical issues. *Johnson v. Thor Motor Coach, Inc.*, 15-cv-85-OC-30PRL, 2016 WL 1182792, *4 (M.D. Fla. Mar. 28, 2016) ("A mechanic's visual inspection may be an acceptable way to identify a defect. In fact, Thor's expert[],

Enoch Hutchcraft [“Hutchcraft”]¹² ..., performed visual inspections to determine whether the slide-out room suffered from a defect.”). Accordingly, the court finds that Bailey meets the “reliability” prong of the *Schneider* test.

*18 Finally, Defendant challenges the “fit” prong of the test, arguing that Bailey's report supplants the role of the jury because of its conclusory nature rather than “assist[ing] the trier of fact.” *Paoli*, 35 F.3d at 742. Defendant does not explain how Bailey's expert report differs from any expert report in terms of assisting the trier of fact. Defendant does not argue that it is irrelevant to the issues of diminished value or faulty repairs; instead, Defendant seems to rehash its arguments as to the “qualifications” and “reliability” prongs. The court finds that Bailey's opinion is relevant, but reminds Defendant that it has the opportunity to “[v]igorous[ly] cross-examin[e Bailey], [and] present[] contrary evidence[] and careful instruction on the burden of proof [which are] the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596, (1993).

ii. Plaintiffs' Challenge to Certain Opinions of Defendant's Expert

In contrast to Defendant's argument that their witness is completely disqualified as an expert, Plaintiffs challenge only five discrete portions of Defendant's expert, Enoch Hutchcraft (“Hutchcraft”), opinion:

- (1) Opinions relating to the slide-outs;
- (2) Opinions relating to warranty analysis and coverage;
- (3) Opinions relating to the water tank;
- (4) Opinions as to whether the warranty was breached; and
- (5) The history of Rvs and “new owner operation”.

(Doc. 49, pp. 1-2.) Plaintiffs' argument related to the slide-outs and the water tank are identical. In both instances, they argue that Hutchcraft admitted in his opinion that he did not inspect either the slide-out or the water tank, and, thus, he should not be permitted to speculate as to any alleged defects. Hutchcraft admits in his deposition that he did not attempt to operate the slide-out or inspect the water tank. (Doc. 59, Exs. B, D.) He does, however, state that he bases his analysis on the repair orders issued by the service centers and a visual inspection of the slide-out without actually operating the slide-out mechanism. (*Id.*) Although the court concludes that this is a sufficient basis to support his opinion on the slide-out and water tank, Plaintiffs are free to attack Hutchcraft's credibility by inquiring as to why he failed to perform visual inspections and operations of those portions of the RV. See *Daubert*, 509 U.S. at 596. Plaintiffs additionally argue that Hutchcraft should be precluded from testifying that certain faults in the RV may be related to “user error” common among new RV owners. The court disagrees. Hutchcraft's experience may have demonstrated to him that certain complications are typically due to user error. Hutchcraft does not definitively state that Plaintiffs caused any damage due to user error, but he may offer his opinion that certain complications present in the RV are typical of those caused by new RV users.

Lastly, Plaintiffs seek to preclude Hutchcraft from testifying as to legal conclusions such as warranty coverage and the ultimate issue of whether the warranty was breached. The court agrees that an expert may not present a legal conclusion or opinion. *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) (An “expert witness is prohibited from rendering a legal opinion.”) Defendant does not contest that Hutchcraft may not opine as to whether the warranty was breached or otherwise interpret the language of the warranty. Accordingly, Plaintiffs motion *in limine* to preclude expert testimony is granted to the extent that it seeks to exclude Hutchcraft's testimony regarding the breach or interpretation of the warranty, but is denied in all other respects.

C. Defendant's Motion to Preclude Video Inspection

In the course of his inspection, Bailey created a video recording of the RV. Defendant now seeks to preclude the admission of the videotape at trial. Defendant argues that the video should be excluded pursuant to [Federal Rule of Evidence 403](#) because its “probative value is substantially outweighed by a danger of ... misleading the jury.” [Fed. R. Evid. 403](#). In support of this argument, Defendant cites to [Fusco v. General Motors Corporation](#), 11 F.3d 259 (3rd Cir. 1993). However, the instant case is readily distinguishable from *Fusco*. In *Fusco*, the defendant attempted to simulate the conditions of a car crash by using a test car on a simulation road course. The Third Circuit held that “[t]he concern lies not with use of tape or film ... but with the deliberate recreation of an event under staged conditions. Where that recreation could easily seem to resemble the actual occurrence, courts have feared that the jurors may be misled because they do not fully appreciate how variations in the surrounding conditions, as between the original occurrence and the staged event, can alter the outcome.” *Id.* at 263-264. Here, the video taken by Bailey was essentially a visual tour of the RV at issue in this case and shows only the portions of the alleged damage that Bailey found relevant. Images of the alleged damages, whether photos or video, are obviously relevant to the issues in this case. Accordingly, Defendant's motion to exclude video evidence will be denied.¹³

D. Plaintiffs' Motion to Omit Discussion of Certain Topics

*19 Styled as a “motion *in limine* regarding improper motives,” Plaintiffs seek to preclude Defendant from addressing three subjects during the course of the trial:

1. [Counsel's] history of representing consumers in lawsuits against recreational vehicle dealers and/or manufacturers;
2. Comments about “greedy lawyers” or similar comments implying that Plaintiffs or their attorneys are pursuing the claims for nefarious or unwholesome reasons (*i.e.*, attorney fees, excessive damages), or other derogatory comments on the motivation of Plaintiffs or their counsel in bringing this case;
3. Comments regarding Plaintiffs' attorney fees and the fee shifting nature of the [MMWA] and the applicable [UTPCPL] claims in this case.¹⁴

(Doc. 47, pp. 1-2.) Counsel for Plaintiffs asserts that, in their experience, numerous similarly situated defendants have attempted to discuss these “improper motives” in an effort to impugn the integrity of plaintiffs and counsel in consumer suits. (Doc. 48, p. 5.) Plaintiffs note that it is error to admit evidence of attorneys fees in a case on the merits. *See Fed. R. Civ. P. 54(d)(2)(A); Walker v. Astrue*, 593 F.3d 274, 279-280 (3d Cir. 2010). It is also improper to make personal attacks on the character or motives of the opposing party, counsel, or witnesses during trial, aside from attempting to impeach the credibility of said witnesses through contradictory evidence. *See Comuso v. AMTRAK*, No. 97-cv-7891, 2000 U.S. Dist. LEXIS 5427, *10-11, 2000 WL 502707 (E.D. Pa. Apr. 25, 2000).

Addressing the first two points in Plaintiffs' motion, Defendant does not disagree that disparaging remarks are improper during trial; however, Defendant notes that it may have occasion to comment on the nature of Plaintiffs' counsel's work in the context of examining expert witnesses. Neither party seems to suggest that being an attorney that practices in the field of consumer protection is, in and of itself, disparaging. Accordingly, Defendant is naturally precluded from disparaging Plaintiffs or their counsel, *e.g.* implying that Plaintiffs are pursuing their claims for “unwholesome reasons” or that counsel is a “greedy lawyer” because of the nature of his practice, but shall not be barred entirely from mentioning the nature of counsel's work in the context of expert witness examination. (*See* Doc. 58, p. 5 (“Bailey has been retained by numerous consumers who have also retained [Counsel]. [Bailey's] bias is subject to robust inquiry at the time of trial and his relationship with Plaintiffs' counsel and other consumer[-]based litigators is a likely product of that inquiry.”).)

*20 Defendant admits that counsel fees and costs are generally not relevant at trial; however, Defendant disagrees that the jury should not be informed of the burden shifting nature of the MMWA and the UTPCPL. Defendant seems to suggest that it “would be irreparably prejudiced if fee shifting/consumer protection statutes cannot be explained in conjunction with the refusal of the last repair opportunity.” (*Id.*) It is unclear in precisely what context Defendant would need to refer specifically to the burden-shifting framework of the MMWA or the UTPCPL and how doing so would not inappropriately suggest that Plaintiffs brought this suit for an improper motive. The court will defer judgment until the pretrial conference in this matter in order to ascertain the precise contours of Defendant's proposed discussion of “the fee shifting/consumer protection statutes ... in conjunction with the refusal of the last repair opportunity.” (*Id.*) Accordingly, the court will deny Plaintiffs' motion *in limine* on this issue without prejudice to renewal at the time of trial.

V. Conclusion

For the reasons set forth above, the court finds that New York law applies to Plaintiffs' claim for an implied warranty and Pennsylvania law applies to all other claims. Because New York law requires privity of contract in order to sustain an implied warranty claim, Defendant's motion for summary judgment will be granted on that claim. The court further finds that Plaintiffs have raised triable issues of fact as to their UTPCPL and express warranty claims, and that Plaintiffs are not barred from recovering damages by the economic loss doctrine. Thus, Defendant's motion for summary judgment will be denied as to those issues.

Addressing the parties motions *in limine*, Plaintiffs' motion to exclude evidence of Bailey's felony convictions is granted and Defendant's motion to admit such convictions is denied. Defendant's motion to exclude Bailey's testimony is denied. Plaintiffs' motion to exclude certain opinions of Hutchcraft is granted to the extent it requests that Hutchcraft be precluded from providing an opinion on legal questions or the ultimate question of breach of the express warranty and is denied in all other respects. Defendant's motion to preclude the video of Bailey's inspection of the RV is denied. Plaintiffs' motion to omit discussion of certain topics at trial is granted with respect to disparaging remarks and evidence of attorneys costs and fees, but is denied without prejudice to renewal at trial with respect to the legal framework of the MMWA and the UTPCPL. Lastly, Plaintiffs' motion requesting that the court follow the procedure to consider attorneys fees after a jury determination on the merits is granted.

An appropriate order will follow.

All Citations

Not Reported in Fed. Supp., 2019 WL 1383509

Footnotes

- 1 The parties have also filed a number of motions *in limine*: Defendant's motion for admission of felony conviction (Doc. 39), Defendant's motion to preclude expert witness (Doc. 41), Defendant's motion to preclude video inspection footage (Doc. 43), Plaintiffs' motion regarding attorney fees, statutory damages, and treble damages (Doc. 45), Plaintiffs' motion regarding improper motives (Doc. 47), Plaintiffs' motion to exclude certain opinion's of Defendant's expert witness (Doc. 49), and Plaintiffs' motion to exclude evidence of a witness' criminal convictions (Doc. 51). These motions in limine have been fully briefed and are addressed herein.
- 2 In *Hammersmith*, the Third Circuit gave a brief historical retrospective on the evolution of choice of law rules in Pennsylvania. Relevantly, the Court of Appeals noted that:

Prior to 1964, Pennsylvania courts uniformly applied the law of the place of contract (“*lex loci contractus*”) or injury (“*lex loci delicti*”) in contract and tort actions, respectively. In *Griffith v. United Air Lines Inc.*, 416 Pa. 1, 203 A.2d 796 (1964), the Pennsylvania Supreme Court expressly abandoned the “*lexi loci delicti*” rule “in favor of a more flexible rule which permits analysis of the policies and interests underlying the particular issue before the court.” *Id.* at 805. Under this new approach, Pennsylvania courts are to apply the law of the forum with the “most interest in the problem,” rather than the law of the place of injury. *Id.* at 806.

Hammersmith, 480 F.3d at 227. The *Hammersmith* court later noted that, although the Pennsylvania Supreme Court has not expressly abandoned the *lex loci contractus* analysis, federal courts predicted that it would do so, and the Pennsylvania Superior Court has so held. See *Budtel Assocs., LP v. Cont'l Cas. Co.*, 915 A.2d 640, 644 (Pa. Super. Ct. 2006); see also *Auto-Owners Ins. Co. v. Stevens & Ricci Inc.*, 835 F.3d 388, 403 (3d Cir. 2016). Relevantly, *Hammersmith* reaffirms that a court performing a choice of law analysis in Pennsylvania may weigh the situs of the contract as a factor in its analysis, but must balance that factor with other interests.

3 In cases involving vehicles, the “location of the subject matter” is generally the location on the day of delivery. See *Powers*, 272 F.R.D. at 423. Also of note, repairs under the express warranty took place in multiple states, at least once in New York and once in Pennsylvania. (Doc. 80, ¶ 27.)

4 Courts in other jurisdictions have reached this same conclusion:

Breach of an express limited warranty provides a federal cause of action under 15 U.S.C. § 2310(d)(1). See *Milicevic v. Fletcher Jones Imports, Ltd.*, 402 F.3d 912, 919 n. 4 (9th Cir. 2005). However, the federal remedies described in 15 U.S.C. § 2304(a) only apply to full warranties. (*Id.*) The [MMWA] is “virtually silent as to the amount and type of damages which may be awarded for breach of an express limited warranty.” *MacKenzie v. Chrysler Corp.*, 607 F.2d 1162, 1166 (5th Cir. 1979). Thus, courts must look to state substantive law to determine the remedies for breach of an express limited warranty.

Gusse v. Damon Corp., 470 F. Supp. 2d 1110, 1116-17 (C.D. Cal. 2007).

5 It is worth noting that the Plaintiffs' actual travel time was less than 12 months because the RV was at various authorized dealers for repair for as many as 62 days. (Hanreck Dep.)

6 See *Gusse*, 470 F. Supp. 2d at 1117 (citing *Milicevic*, 402 F. 3d at 919 n.4); see also *Vullings v. Bryant Heating & Cooling Sys.*, No. 18-cv-3317, 2019 WL 687881, *2 (E.D. Pa. Feb. 19, 2019) (“[The MMWA] does not contain a statute of limitations, so courts apply the most analogous state law period”).

7 Plaintiffs do not address Defendant's argument that warranty coverage was waived when the Plaintiffs cancelled their scheduled factory repair. In *Woolums*, the court excluded damages that were never reported to the manufacturer under the warranty and, thus, were not given an opportunity to be repaired. In contrast, here, the repairs sought at the factory had previously been addressed at service centers but were not adequately addressed by those repairs. Accordingly, Plaintiffs may only rely upon evidence of those repairs scheduled for a factory repair to the extent they support a claim that the repairs were not timely completed prior to the scheduled factory repair.

8 Defendant also argues that Plaintiffs should be precluded from seeking redress under the UTPCPL because they are not residents of Pennsylvania and the only activities “touching” on the Commonwealth were the repairs conducted at the Camping World in Harrisburg. (Doc. 38, p. 27.) Defendant, however, cites no precedent or statutory language that would imply a minimum number of contacts with the Commonwealth in order to trigger the protections of the statute. Accordingly, this court rejects Defendant's argument that Plaintiffs may not invoke the UTPCPL based solely on their limited activities in Pennsylvania.

- 9 Moreover, even had the economic loss doctrine applied here, Plaintiffs claims would only be partially dismissed on those grounds because Plaintiff's claims under the UTPCPL raise deceptive practices outside the four corners of the warranty.
- 10 Defendant styled its motion *in limine* as a motion "Seeking Admission of the Felony Conviction," while Plaintiffs filed a motion titled "Motion *in Limine* to Exclude Evidence of [Bailey's] Criminal Convictions." Plaintiffs contend that Defendant's position is improper for a motion *in limine* and should be dismissed summarily. Because the parties have filed largely duplicative motions, the court need not address whether Defendant's is "improper;" the analysis under Rule 609 is identical regardless of the motion *in limine's* title.
- 11 By way of example, factors employed in his diminished value report include: "1. Service records reviewed if available or applicable; 2. Personal inspection of overall condition; 3. Consideration of floor plan; 4. Type of vehicle; 5. Estimated or actual mileage on RV; 6. Options-non-forced; 7. Evidence or prior or existing damage ..." (Doc. 62, Ex. 1D.)
- 12 It is worth noting that the expert in *Thor* is the expert currently employed by Defendant.
- 13 In its reply brief, Defendant states that they demand that "the motor home [be presented] at the time of trial." (Doc. 70, p. 3.) However, this single sentence in an otherwise unrelated motion is not sufficient to inform the court of this request. If Defendant desires that a visit to the RV be arranged for the jury, it should address such a request and the logistical concerns attendant thereto by separate motion.
- 14 Vexingly, Plaintiffs filed an additional "motion *in limine*" requesting that the court wait until the close of a trial on the merits to address the issues of attorneys fees and other special damages available under the MMWA or the UTPCPL. (Doc. 45.) The motion itself mentions only precluding the discussion of attorneys fees and the burden-shifting nature of the MMWA and UTPCPL at trial, yet this is redundant with point three of Plaintiffs' "improper motives" motion *in limine*. The brief in support of the motion, however, largely recites the procedural standard for an award of attorneys fees in cases where the court, rather than the jury, determines the propriety of special damages and fee awards. There is no indication that Defendant intended otherwise, and Defendant does not disagree that this is the proper method in this case. Although such a motion appears redundant and unnecessary, to the extent Plaintiffs request reassurance that the court will follow the proper procedure for considering a petition for attorneys fees following a trial on the merits, the court will grant the motion.

2021 WL 6051382

United States District Court, E.D. Pennsylvania.

John J. “Gus” HOEFLING and Margaret Hoefling, his wife, Plaintiffs,

v.

U.S. SMOKELESS TOBACCO CO., LLC; and [Pinkerton Tobacco Co., LP](#), Defendants

CIVIL ACTION NO. 19-3847

|

Filed 12/21/2021

Synopsis

Background: Patient, who had been diagnosed with squamous cell carcinoma of the left tonsil, and his wife brought product liability action against smokeless tobacco manufacturers for claims of defective design, failure to warn, and loss of consortium under Pennsylvania law. Manufacturers moved to exclude medical causation opinions of experts and for summary judgment.

Holdings: The District Court, [Gerald J. Pappert](#), J., held that:

- [1] sources that radiation oncologist relied upon did not support opinion that smokeless tobacco caused tonsil cancer;
- [2] oncologist failed to consider literature as a whole when opining on general causation;
- [3] oncologist failed to account for absence of data supporting theory of general causation;
- [4] oncologist's opinion on general causation did not fit facts of case;
- [5] cancer expert's opinion was unduly reliant on assumptions drawn from biological plausibility;
- [6] experts failed to conduct proper differential etiology to support opinion on specific causation; and
- [7] experts failed to testify to “reasonable degree of medical certainty,” as necessary to establish specific medical causation.

Motions granted.

Procedural Posture(s): Motion to Exclude Expert Report or Testimony; Motion for Summary Judgment.

West Headnotes (43)

[1] **Products Liability** 🔑 **Proximate Cause**

To prevail on a product liability claim, a plaintiff must prove general and specific causation.

[2] **Products Liability** 🔑 **Proximate Cause**

General causation, for purposes of a product liability claim, addresses whether the product is capable of causing a particular injury or condition in the general population, and specific causation goes to whether it caused a particular individual's injury.

[3] **Products Liability** 🔑 Proximate Cause

A plaintiff bringing a product liability claim must establish general causation before moving to specific causation.

[4] **Evidence** 🔑 Gatekeeping in general

Evidence 🔑 Speculation, guess, or conjecture; probability or possibility

Faced with a proffer of expert scientific testimony, the district court acts as a gatekeeper to ensure that the expert's opinion is based on the methods and procedures of science rather than on subjective belief or unsupported speculation. [Fed. R. Evid. 702](#).

[5] **Evidence** 🔑 Determination as to basis of expert's opinion and reliability in general

Federal Courts 🔑 Expert evidence and witnesses

The rule governing the admission of expert testimony grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case. [Fed. R. Evid. 702](#).

[6] **Evidence** 🔑 Correctness or soundness

Evidence 🔑 Reliability

To obtain admission of expert testimony, the expert's proponents do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable. [Fed. R. Evid. 702](#).

[7] **Evidence** 🔑 Factors, Tests, and Standards in General

When considering whether expert testimony is reliable, relevant factors include: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. [Fed. R. Evid. 702](#).

[8] **Evidence** 🔑 Means of attacking expert

As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process, meaning competing expert testimony and active cross-examination, rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies. [Fed. R. Evid. 702](#).

[9] **Evidence** 🔑 Daubert and Frye tests in general

Daubert and the rule governing admission of expert testimony put their faith in an adversary system designed to expose flawed expertise. [Fed. R. Evid. 702](#).

[10] **Evidence** 🔑 Relevance and materiality

The “fit” requirement for admissibility of expert testimony means that the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. [Fed. R. Evid. 702](#).

[11] **Evidence** 🔑 Relevance and materiality

The “fit” requirement for admission of expert testimony goes primarily to relevance; expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. [Fed. R. Evid. 702](#).

[12] **Evidence** 🔑 Relevance and materiality

The “fit” between proffered expert testimony and the case at hand, as a requirement for such testimony's admission, is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. [Fed. R. Evid. 702](#).

[13] **Evidence** 🔑 Products liability in general

Sources that expert, a radiation oncologist, relied on did not support his proffered opinion that smokeless tobacco caused tonsil cancer, weighing against admission of opinion at trial on cancer patient's products liability claims against tobacco manufacturers; reports by World Health Organization (WHO) and United States Surgeon General discussing associations between smokeless tobacco and oral-cavity, esophageal, and pancreatic cancer did not conclude smokeless tobacco caused tonsil or oropharyngeal cancer, and Surgeon General report stated there was sparse evidence of any association between smokeless tobacco use and cancers outside oral cavity. [Fed. R. Evid. 702](#).

[14] **Evidence** 🔑 Products liability in general

In opining that smokeless tobacco caused tonsil cancer, expert, a radiation oncologist, ignored information and research rather than considering the literature as a whole, weighing against admission of opinion on causation at trial on cancer patient's products liability claims against tobacco manufacturers; expert did not do in-depth review of any epidemiological research published in recent decades, and did not independently review epidemiological research cited by reports which he purported to rely upon but which did not in fact justify his opinion, including study described as largest and most comprehensive study on smokeless tobacco products and their associations with head and neck cancers. [Fed. R. Evid. 702](#).

[15] **Evidence** 🔑 Opinions, records, or reports of others

An expert must examine the literature as a whole to draw a causal conclusion. [Fed. R. Evid. 702](#).

[16] **Products Liability** 🔑 Proximate Cause

Products Liability 🔑 Chemicals in general

“Biological plausibility,” which can be important when determining general causation of a disease at issue in a products liability case, is defined as a judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology. [Fed. R. Evid. 702](#).

[17] **Evidence** 🔑 Factors, Tests, and Standards in General

Expert testimony should not be excluded simply because there is no literature on point provided there are other factors that demonstrate the reliability of the expert's methodology. [Fed. R. Evid. 702](#).

[18] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

The best evidence of general causation in a toxic tort case is epidemiology, and when available it cannot be ignored.

[19] **Evidence** 🔑 Products liability in general

Opinion by expert, a radiation oncologist, that it was biologically plausible for smokeless tobacco to cause tonsil cancer failed to account for absence of data to support such general causation, weighing against admission of opinion at trial on patient's products liability claims against tobacco manufacturer; expert testified that use of smokeless tobacco, which was held in back of oral cavity near oropharynx, could cause saliva containing carcinogens to “bathe” tonsil, but no epidemiological research established such causal link, rendering opinion speculative, and expert's explanation that it was difficult to distinguish smokeless tobacco's causative role from roles of confounders did not explain why existing research or lack thereof did not contradict or undermine his opinion. [Fed. R. Evid. 702](#).

[20] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

In a toxic tort case, expert causation testimony generally should be supported by positive and replicated epidemiological studies. [Fed. R. Evid. 702](#).

[21] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

In a toxic tort case, when an expert's causation opinion is equivocal or inconsistent with epidemiological research, the expert must thoroughly analyze its strengths and weaknesses. [Fed. R. Evid. 702](#).

[22] **Evidence** 🔑 Ipse dixit

Neither *Daubert* nor the rule governing admission of expert opinions require a district court to admit an expert's opinion that is connected to existing data solely by the expert's ipse dixit. [Fed. R. Evid. 702](#).

[23] **Evidence** 🔑 Cause

Opinion of expert, a radiation oncologist, that smokeless tobacco could cause tonsil cancer did not fit facts of patient's products liability action against tobacco manufacturers, and, thus, admission of opinion would not help trier of fact determine causation; different types of smokeless tobacco products carried different oral cancer risks, expert's general causation opinion was independent of specific products at issue, and in developing opinion, expert did not separate moist snuff from loose leaf chewing tobacco. [Fed. R. Evid. 702\(a\)](#).

[24] **Evidence** 🔑 Products liability in general

Cancer expert failed to adequately consider relevant literature in developing his opinion that smokeless tobacco caused oropharyngeal cancer, weighing against admissibility of such opinion at trial on tonsil cancer patient's products liability claims against tobacco manufacturers, where significant part of cancer expert's purported literature review consisted of background reading in medical textbooks, and at deposition, expert clarified that finding cited in his report that smokeless tobacco use multiplied risk of oropharyngeal cancer risk by more than ten actually only applied to mouth and gum cancers, and expert relied on selected subset of literature without sufficient analysis of contrary literature. [Fed. R. Evid. 702](#).

[25] **Evidence** 🔑 Products liability in general

Cancer expert's opinion that smokeless tobacco caused tonsil cancer was unduly reliant on assumptions drawn from biological plausibility, rather than being grounded in sound reasoning and methodology, and, thus, opinion was insufficiently reliable to be admissible at trial on cancer patient's products liability claims against tobacco manufacturers, where expert merely assumed that pharynx was exposed to carcinogenic material from smokeless tobacco and cited to general knowledge in his field that smokeless tobacco caused oral cancer, but there was a dearth of epidemiological research to support such theory of general causation, and expert conflated oral cancer and tonsil cancer due to small number of cases of tonsil cancer. [Fed. R. Evid. 702](#).

[26] **Evidence** 🔑 Cause

Opinions of smokeless tobacco expert that using moist snuff or loose leaf chewing tobacco caused cancer in humans and that snuff product and loose leaf tobacco product at issue in tonsil cancer patient's products liability action against manufacturers contained high levels of tobacco-specific nitrosamines (TSNAs), which were carcinogenic, did not assist trier of fact in determining whether products at issue could cause tonsil cancer, and, thus, opinions lacked sufficient "fit" to facts of case to be admissible on issue of general causation; carcinogen exposure in general was not, by itself, guarantee of cancer formation, and expert did not address tonsil cancer in particular. [Fed. R. Evid. 702](#).

[27] **Evidence** 🔑 Products liability in general

Smokeless tobacco expert's opinion that smokeless tobacco could cause tonsil cancer was impermissibly based on speculation arising from biological plausibility, rather than scientific principles and methodology, and, thus, opinion was not admissible at trial on tonsil cancer patient's products liability claims against tobacco manufacturers, where expert based opinion on analogy to cancers of oral cavity and assumption that carcinogens would contact tonsils, but expert did not address literature stating that smokeless tobacco was not associated with increased risk of oropharyngeal cancer, and expert's methods were untested, lacked standards controlling their operation, and were unmoored from epidemiological data. [Fed. R. Evid. 702](#).

[28] **Evidence** 🔑 Causation

A general causation expert must address both supportive and contrary evidence when forming an opinion. [Fed. R. Evid. 702](#).

[29] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

In a toxic tort case, physicians may base their opinions on the cause of a person's illness on a properly performed differential etiology; when conducting such an analysis, an expert must “rule in” then “rule out” possible causes of illness. [Fed. R. Evid. 702](#).

[30] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

In a toxic tort case, when basing their opinions on the cause of a person's illness on a differential etiology, experts are not required to address all possible causes, but obvious alternative causes need to be ruled out. [Fed. R. Evid. 702](#).

[31] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

In a toxic tort case where a plaintiff's expert bases his or her opinion on the cause of the plaintiff's illness on a differential etiology, once the defendant points to plausible alternative cause of the plaintiff's illness, the expert must offer a good explanation as to why his or her conclusion remains reliable. [Fed. R. Evid. 702](#).

[32] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

In a toxic tort case, an expert physician need not perform every possible test to confirm his opinion as to specific causation, but he must employ sufficient diagnostic techniques to have good grounds for his conclusion. [Fed. R. Evid. 702](#).

[33] **Evidence** 🔑 Products liability in general

Physicians' opinion that patient's tonsil cancer was caused by smokeless tobacco was based on improper differential etiology to rule in, then rule out different possible causes; physicians refused to rule in human papillomavirus (HPV), which was predominant cause of tonsil cancer, without overwhelming evidence that patient had HPV, but absence of positive HPV test was not evidence HPV was absent, given that HPV was common and it was unlikely HPV would have been detected before male patient's cancer diagnosis, one physician failed to methodically rule out alternative causes, no tumor biopsy ruled out HPV, and alternative grounds physicians invoked for discounting HPV as cause, including patient's age and tobacco use and assumptions about his sexual history, lacked scientific reliability. [Fed. R. Evid. 702](#).

[34] **Federal Civil Procedure** 🔑 Burden of proof

Federal Civil Procedure 🔑 Weight and sufficiency

A mere scintilla of evidence supporting the nonmoving party will not suffice to defeat a motion for summary judgment; rather, the nonmovant must set forth specific facts showing that there is a genuine issue for trial. [Fed. R. Civ. P. 56](#).

[35] **Federal Civil Procedure** 🔑 Weight and sufficiency

Federal Civil Procedure 🔑 Ascertaining existence of fact issue

On a motion for summary judgment, although a court must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor, it need not credit unsupported assertions, conclusory allegations, or mere suspicions, nor may it make credibility determinations or weigh the evidence. [Fed. R. Civ. P. 56](#).

[36] **Health** 🔑 Proximate cause

Expert testimony is generally required to prove causation of a medical condition.

[37] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

Under Pennsylvania law, experts on medical causation in a toxic tort case must testify to a reasonable degree of medical certainty.

[38] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

The requirement, under Pennsylvania toxic tort law, that experts on medical causation of an injury testify to a reasonable degree of medical certainty is not merely an evidentiary requirement; it forms part of the plaintiff's burden of proof.

[39] **Federal Civil Procedure** 🔑 Tort cases in general

If a plaintiff in a toxic tort case under Pennsylvania law lacks evidence to satisfy the standard for medical causation, namely testimony to a reasonable degree of medical certainty, summary judgment is appropriate.

[40] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

Whether an expert testifying on medical causation in a toxic tort case under Pennsylvania law satisfies the “reasonable degree of medical certainty” standard does not depend on magic words; instead, the court determines whether the

expert's testimony, taken as a whole, is based on a reasonable degree of medical certainty rather than upon mere speculation.

[41] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

Testimony that something was “more likely than not” the cause of a plaintiff's injury is insufficient to satisfy the “reasonable degree of medical certainty” standard for medical causation testimony under Pennsylvania toxic tort law.

[42] **Negligence** 🔑 In general; degrees of proof

Products Liability 🔑 Chemicals in general

Products Liability 🔑 Proximate Cause

An expert testifying as to the medical causation of a plaintiff's injury in a toxic tort case under Pennsylvania law does not express the requisite “reasonable degree of medical certainty” when the expert puts the odds in favor of his theory of causation at just above fifty-fifty.

[43] **Evidence** 🔑 Causation

Products Liability 🔑 Tobacco products

Products Liability 🔑 Proximate Cause

Radiation oncologist's and cancer expert's testimony that smokeless tobacco caused patient's tonsil cancer failed to satisfy “reasonable degree of medical certainty” standard for medical causation under Pennsylvania law, and, thus, did not establish specific causation element of patient's products liability claims against tobacco manufacturers, where oncologist testified there was “equal probability” that either smokeless tobacco or human papillomavirus (HPV) caused patient's cancer and could not say either was “likely” the cause of patient's cancer, and cancer expert similarly expressed his opinion on causation in terms of probability hovering near 50%.

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MEMORANDUM

PAPPERT, District Judge

*1 John J. “Gus” Hoefling used smokeless tobacco for more than thirty years. He claims Red Man, a loose leaf chewing tobacco manufactured by Pinkerton Tobacco Co. LP, and Skoal, a moist snuff manufactured by U.S. Smokeless Tobacco Company, caused the squamous cell [carcinoma](#) on his left tonsil. He believes the [cancer](#) is the result of Defendants’ defectively designed products and their failure to adequately warn him about known risks associated with Red Man and Skoal. His wife, Margaret “Maggie” Hoefling, asserts a claim for loss of consortium.

Pinkerton and U.S. Smokeless move to exclude the medical causation opinions of Drs. Paul Busse, Bruce Chabner and Scott Tomar. Dr. Tomar offers an opinion on general causation only, while Drs. Busse and Chabner also claim that Defendants’ products specifically caused Hoefling’s [tonsil cancer](#). Pinkerton and U.S. Smokeless acknowledge the experts’ qualifications but argue their opinions are not reliable and do not fit the facts of this case. *See* (ECF 71, 74 and 76). Because Hoefling needs their opinions to prove that Pinkerton or U.S. Smokeless caused his [tonsil cancer](#), Defendants have also filed motions for summary judgment. (ECF 73 and 75.) After a thorough review of the record and oral argument, the Court grants Defendants’ motions to exclude all three causation experts’ opinions. Absent those opinions, no reasonable jury could return a verdict in the Hoeflings’ favor so the Court also grants Pinkerton’s and U.S. Smokeless’s summary judgment motions. Even if the Court allowed the experts’ opinions, it would still enter judgment for the Defendants because the Hoeflings could not prove causation under Pennsylvania law.

I

A

Hoefling first tried Red Man in 1973, when he was thirty-eight or thirty-nine. (U.S. Smokeless SOMF, ECF 75-2, ¶ 8.) Red Man is a type of chewing tobacco made from chopped, cured loose tobacco leaves. (Pinkerton SOMF, ECF 73-8, ¶ 38.) He used Skoal for the first time in 1976 or 1977. (*Id.* ¶ 15.) Skoal is a type of moist snuff made from finely ground or shredded tobacco leaves that are fermented during the curing process. (*Id.* ¶ 38.) Skoal became Hoefling’s “primary tobacco,” but he still used Red Man. (*Id.* ¶ 8.) Specifically, he used two to five cans of Skoal and chewed three bags of Red Man each week. (Hoefling Resp. to Pinkerton Interrog. No. 2, ECF 75-7 at 4.) When he began using the products, they bore “no warnings” and Hoefling “had no idea [he] would become addicted.” (Hoefling Dep., ECF 75-6, at 317:10–13; 384:4.)

Since 1987, federal law has required smokeless tobacco packages to bear one of three warnings: (1) WARNING: THIS PRODUCT MAY CAUSE [MOUTH CANCER](#); (2) WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS; (3) WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES. *See (id., ¶ 64; U.S. Smokeless SOMF, ¶ 29).* Hoefling saw, read and was aware of warnings on Skoal and Red Man since the warnings’ inception. (Pinkerton SOMF, ¶ 65; U.S. Smokeless SOMF, ¶ 30.) Nevertheless, he did not quit until 2011, when he was seventy-seven, after asking the cashier who typically sold him smokeless tobacco at his local gas station not to sell him “any more Red Man.” (U.S. Smokeless SOMF, ¶¶ 20–21.) He decided he “was being totally controlled by the product It was affecting [his] life,” he believed “it would start to affect his marriage” and “[i]t was certainly going to affect [his] health.” (Hoefling Dep., 364:16–24.)

B

*2 In December 2018, when Hoefling was eighty-six, he was diagnosed with squamous cell [carcinoma](#) of the left tonsil. (Pinkerton SOMF, ¶ 18.) He underwent radiation treatment and, in November 2019, imaging showed previous “mild activity” in his left tonsillar region “at background compatible with treated malignancy,” with no evidence of recurrence. (*Id.*)

Alcohol, smoking and human papillomavirus (“HPV”) infection are acknowledged risk factors for [tonsil cancer](#). (*Id.* ¶ 19.) Hoefling alleges he never consumed alcohol and there is no record evidence to the contrary. *See* (Am. Compl., ECF 13, ¶ 64). In addition to using smokeless tobacco, Hoefling smoked cigarettes in high school at least occasionally. (Pls.’ Resp. to Pinkerton SOME, ECF 85-15, ¶ 13.) His medical records suggest he may have smoked after that, but no witness testimony corroborates those records. (*Id.*)

HPV causes eighty percent of [tonsil cancers](#) and seventy percent of [cancers](#) occurring in the oropharynx, which is part of the pharynx and behind the oral cavity. (Pinkerton SOME, ¶ 92; Mundt. Rpt., ECF 76-13 at 5 (presenting anatomical diagram of throat, mouth and nose).) Crucially, no one knows if Hoefling’s tumor was HPV positive; a [fine-needle biopsy](#) taken when he was diagnosed had insufficient cellularity to permit a test to rule out HPV as the cause. (*Id.* ¶ 20.) No further biopsy was ordered. (*Id.* ¶ 21.)

C

After Hoefling’s diagnosis, he and his wife sued Pinkerton, U.S. Smokeless and others in the Philadelphia County Court of Common Pleas, and U.S. Smokeless removed the case to this Court. (ECF 1.) The Hoeflings then amended their Complaint, leaving U.S. Smokeless and Pinkerton as the only defendants. (ECF 13.) They also voluntarily dismissed Hoefling’s fraud and negligent misrepresentation claims (ECF 21 at 12) and stipulated to limit his general negligence claim to theories based on an alleged failure to warn or certain design defects. (ECF 33 at 3.) The Court dismissed the Hoeflings’ conspiracy claim without prejudice. (ECF 34.) It then denied U.S. Smokeless’s motion seeking to transfer venue to the Middle District of Florida. (ECF 63, 64.) They only claims remaining are for failure to warn and design defect (both in negligence and strict liability) (Counts I–IV) and loss of consortium (Count VIII).

II

[1] [2] [3] To prevail on his product liability claims, Hoefling must prove general and specific causation. *See In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016) (*Zolofit III*) (citing *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377–78 (5th Cir. 2010)); *see also Paoli*, 35 F.3d at 752 (explaining plaintiffs must show the product “can cause the types of harm they suffered, and that the [product] in fact did cause them harm”). General causation addresses whether a product is “capable of causing a particular injury or condition in the general population,” and specific causation goes to whether it “caused a particular individual’s injury.” *Zolofit III*, 176 F. Supp. 3d at 491. Hoefling “must establish general causation before moving to specific causation.” *Id.* (noting plaintiff’s claim fails absent “predicate proof of general causation”).

A

[4] Hoefling “must present admissible expert testimony” to prove causation because this case “involv[es] complex issues of causation not readily apparent to the finder of fact.” *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003). In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that “[f]aced with a proffer of expert scientific testimony ... the trial judge must determine at the outset ... whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” 509 U.S. 579, 592, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). In *Kumho Tire Co. v. Carmichael*, the Supreme Court made clear that the Court’s *Daubert* gatekeeping function extends beyond scientific testimony to include testimony based on “technical” and “other specialized knowledge.” 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). The district court acts “as a gatekeeper to ensure that the expert’s opinion is based on the methods and procedures of science rather than on subjective belief or unsupported speculation.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012) (internal quotations omitted). *Daubert* “focuses on principles and methodology, not

on the conclusions generated by principles and methodology.” *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000).

*3 Thus, a witness with “knowledge, skill, experience, training, or education” to qualify as an expert

may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 embodies “a trilogy of restrictions on expert testimony: qualification, reliability and fit.” *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). U.S. Smokeless and Pinkerton seek to exclude the general causation opinions of Drs. Busse, Chabner and Tomar and Busse and Chabner's specific causation opinions.¹ Their qualifications are not at issue.² U.S. Smokeless and Pinkerton contest only their opinions’ reliability and fit.

[5] [6] [7] [8] [9] *Daubert's* “reliability analysis ... applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion.” *ZF Meritor*, 696 F.3d at 291 (internal quotations omitted). “Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case.” *Kumho Tire*, 526 U.S. at 158, 119 S.Ct. 1167. An expert's proponents “do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). When considering whether expert testimony is reliable, relevant factors include:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

*4 *U.S. v. Mitchell*, 365 F.3d 215, 235 (3d Cir. 2004) (citation omitted). “As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.” *Id.* at 244 (citations and internal quotation omitted). “Rule 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise.” *Id.* at 244–45.

[10] [11] [12] The “fit” requirement means “the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Schneider*, 320 F.3d at 404. Fit “... goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591, 113 S.Ct. 2786 (citations and internal quotations omitted). “ ‘Fit’ is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.*

B

1

Dr. Busse's general causation opinion is not reliable. His expert report summarizes his opinions' basis: (1) The WHO's International Agency for Research on Cancer ("IARC") concluded "[s]mokeless tobacco causes [cancers of the oral cavity](#)"; (2) the U.S. Surgeon General determined smokeless tobacco "can cause [cancer](#) and a number of non-cancerous oral conditions and can lead to nicotine addiction and dependence"; (3) the American Academy of Otolaryngology ("AAO") and CDC determined "smokeless tobacco products contain [cancer](#) causing chemicals," the most harmful of which include tobacco-specific nitrosamines ("TSNAs"); and (4) every "major public health organization," such as the WHO, American Cancer Society and National Cancer Institute, has identified smokeless tobacco as a "cause of [oral cancer](#)." (Busse Rpt., ECF 71-5 at 4 (internal quotations omitted).)

[13] The sources Dr. Busse relies on do not support his opinion that smokeless tobacco, including Skoal and Red Man, can in general cause [tonsil cancer](#). This violates *Daubert*'s requirement that his opinion rest upon "good grounds." *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786). The IARC did not conclude smokeless tobacco causes tonsil or oropharyngeal [cancer](#). (Busse Dep., ECF 71-3 at 113:7–23, 115:2–116:16; Chabner Dep., ECF 71-4 at 83:1–20; Tomar Dep., ECF 70-2 at 184:1–185:24). It found a causative link only to oral-cavity, esophageal and [pancreatic cancer](#). (*Id.*) Moreover, the 1986 Surgeon General report pointed to evidence that using snuff can cause [cancer](#), with the "strongest" evidence for [oral-cavity cancer](#). (ECF 71-2, ¶ 2.) But it did not conclude smokeless tobacco causes [oropharyngeal cancer](#). (*Id.*) In fact, it stated there was "sparse" evidence of any association between "smokeless tobacco use and [cancers](#) outside of the oral cavity." (Busse Dep. at 128:15–17.) The tonsil is in the oropharynx, not the oral cavity. Patients are not diagnosed with "[head and neck cancer](#)" but rather [cancers](#) of more narrowly defined anatomical sites, which have different risks—including the oropharynx or tonsil. See (Chabner Dep. at 152:6–22).³

*5 [14] [15] In addition to relying on multiple sources that do not justify his view, Dr. Busse ignores other information and research. Causal conclusions require examining "the literature as a whole." *In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 461 (E.D. Pa. 2014) (*Zolofit I*) (explaining the "accepted scientific practice" is not for experts to "simply ignor[e] certain studies" but rather explain why they "give[] more weight" to particular studies when forming an opinion). In forming his general causation opinion, Dr. Busse relied on the authorities he cites in his report, case-specific documents like Hoefling's medical records and a 1981 article based on a study of 255 women in North Carolina. (Busse Dep. at 59:1–17; Busse Rpt. at 2; Winn Art., ECF 71-9.) He did not do an "in depth" review of any epidemiological research published after 1981. (Busse Dep. at 55:22–24.) Nor did he independently review the epidemiological research cited by the Surgeon General report or IARC. (*Id.* at 58:20–24.) Dr. Busse did not review the 2016 Wyss study, which Dr. Chabner described as one of the "more complete" articles on smokeless tobacco products and Dr. Tomar characterized as the most "on point" for his work on this case. (*Id.* at 55:3–5; Chabner Dep. at 77:17–20; Tomar Dep. at 188:7–12.) The study pooled data from eleven case-controlled studies of pharyngeal, laryngeal and [oral cancers](#) and, importantly, controlled for cigarette smoking—a common "confounder" in studies of smokeless tobacco products—to estimate "associations between smokeless tobacco products and [[head and neck cancer](#)], including associations for exclusive use of smokeless tobacco products and associations with specific tumor sites." (Wyss Study, ECF 71-11 at 703–04; Tomar Dep. at 191:8–12.) It was the "largest and most comprehensive study to date" to make these estimations. (Wyss Study at 713.) Unlike the general causation expert who "explain[ed] at length why he favors" one study over another, Dr. Busse did not even consider the Wyss study. *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 660 (E.D. Pa. 2012).

[16] Dr. Busse's general causation opinion is also unreliable because it is based on "biological plausibility" and lacks support from epidemiological data. Biological plausibility is defined as a "judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology." *In re Fosamax Prods. Liab. Litig.*, 645 F.

Supp. 2d 164, 181 (S.D.N.Y. 2009) (citing Michael D. Green et al., *Reference Guide on Epidemiology* at 388 in Federal Judicial Center, *Reference Manual on Scientific Evidence* (2d ed. 2000)). Biological plausibility can be important when determining general causation. See, e.g., *Soldo*, 244 F. Supp. 2d at 569 (noting biological plausibility is one of the Bradford-Hill criteria used to evaluate general causation when there is a demonstrated epidemiological association).⁴

[17] [18] Expert testimony “should not be excluded simply because there is no literature on point” provided there are “other factors that demonstrate the reliability of the expert’s methodology.” *Schneider*, 320 F.3d at 406; see *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999) (explaining a medical expert need not “always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness”). But the “best evidence of general causation in a toxic tort case” is epidemiology, and when available it “cannot be ignored.” *Zolof III*, 176 F. Supp. 3d at 492 (quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005)); see also *Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 483 (W.D. Pa. 2010) (defining epidemiology as the “primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease” (internal quotations omitted)).

*6 [19] Dr. Busse’s belief that it is biologically plausible for smokeless tobacco products like Red Man or Skoal to cause tonsil cancer does not account for the absence of data to support general causation. He testified smokeless tobacco is held in the “back of your oral cavity, and it causes cancer” there as well as in the esophagus, so saliva containing carcinogens must “bath[e]” the tonsil given the oropharynx connects the oral cavity to the esophagus. (Busse Dep. at 123:24–124:12); see (*id.* at 61:2–9 (explaining part of the tonsil is below the oral cavity and “downstream” of saliva flow)). Dr. Busse said this opinion followed from anatomy and “common sense” and agreed it was based on “biological[] plausib[ility].” (*Id.* at 123:24–124:17.)

He acknowledges, however, the lack of epidemiological research establishing the necessary causal link between smokeless tobacco and tonsil cancer. Dr. Busse testified using “chewed tobacco” or “smokeless tobacco” is a risk for “head and neck cancers” but that it is “really tough” to “isolat[e]” smokeless tobacco’s role in studies because “the data just aren’t there.” (*Id.* at 56:10–17.) He explained “teasing out” smokeless tobacco as a “unique” or “monolithic” cause of oropharyngeal cancer is “just about impossible” because smokeless tobacco consumers also tend to consume other tobacco products, like cigarettes. See (*id.* at 119:23–120:2, 213:23–214:11). He nonetheless estimates the risk of developing tonsil cancer from smokeless tobacco use is one and a half, compared to a baseline of one. (*Id.* at 57:3–15.) But see *Pritchard*, 705 F. Supp. 2d at 486 (noting courts that “refused to consider” epidemiological research with a relative risk less than two to support an “association between a chemical agent and a disease”). Dr. Busse separately described the risk of tonsil or oropharyngeal cancer associated with smokeless tobacco as “some glimmer” but stated it is “small.” (Busse Dep. at 214:16–24.)

[20] [21] [22] Expert causation testimony “generally should be supported by positive and replicated epidemiological studies.” *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 475 (E.D. Pa. 2014) (*Zolof II*). When an expert’s causation opinion is “equivocal or inconsistent with” epidemiological research, the expert must “thoroughly analyze” its “strengths and weaknesses.” *Id.* Dr. Busse did not do so. He attempts to reconcile his general causation opinion with existing research by pointing to the difficulty of distinguishing smokeless tobacco’s role from those of confounders. But this fails to sufficiently explain why the existing research—or lack thereof—“does not contradict or undermine” his opinion. *Id.* Instead, Dr. Busse makes “speculative leaps” in claiming that a causal link exists simply because it is biologically plausible. *Id.* at 481 (explaining that not even “genuinely talented” experts can testify to “unscientific speculation”). Neither *Daubert* nor Rule 702 require the Court to admit an expert’s opinion that is “connected to existing data” solely by the expert’s “ipse dixit.” *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (emphasis in original) (stating the Court is free to conclude “there is simply too great an analytical gap between the data and the opinion proffered”); see also *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. 18-2848, 2021 WL 5631687, at *7 (E.D. Pa. Dec. 1, 2021) (explaining *Daubert* requires “[r]eliable expert medical testimony” rather than “lay assumptions or guesswork”).

Dr. Busse’s opinion on general causation is also unreliable because it is not the product of a scientific methodology. Rule 702 requires his opinion to be grounded in “methods and procedures of science” instead of “subjective belief or unsupported speculation.” *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786). Scientific methods are “based on

generating hypotheses and testing them to see if they can be falsified.” *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786 (internal quotation marks omitted). But it is “impossible to test a hypothesis” produced by a subjective methodology because only its “creator” can “test[] or falsify[]” it. *TMI*, 193 F.3d at 703 n.144; see also *Paoli*, 35 F.3d at 742 n.8 (listing “whether a method consists of a testable hypothesis” as one of the eight factors the Third Circuit has adopted for assessing reliability); cf. *Soldo*, 244 F. Supp. 2d at 451, 533 (noting epidemiology is “by its very nature ‘testable,’ ” because it has “methods and standards” and that its “very purpose” is serving the “type of testing function required by *Daubert*”).

*7 Dr. Busse implies one reason a causal relationship between smokeless tobacco products and **tonsil cancer** has not been established is the difficulty of “teasing out” smokeless tobacco’s role. (Busse Dep. at 119:23–120:4.) So understood, his view that Red Man or Skoal can cause **tonsil cancer** is not reliable because it is nothing more than an “untested hypothesis.” *Zolof II*, 26 F. Supp. 3d at 473; cf. *Zolof III*, 176 F. Supp. 3d at 495 (explaining a proposed expert’s statement of “reasons why a particular study may not have found a positive association” “falls far short of establishing causation”). Alternatively, Dr. Busse’s view is not scientific because it is “mere subjective belief” propped up by biological plausibility rather than an “objective inference[] from the relevant scientific evidence”—which does not draw the necessary causal connection between Defendants’ smokeless tobacco products and **tonsil cancer**. *Soldo*, 244 F. Supp. 2d at 504–05. Decisions “based on less than sufficient and/or reliable scientific evidence” are “guesses” that “do not constitute a scientifically reliable approach” for evaluating causation. *Id.* at 505.

2

[23] Dr. Busse’s general causation opinion also does not fit the facts of this case. There are many smokeless tobacco product types, and they carry different risks. (Pinkerton SOMF ¶ 36); see also (Murrelle Rpt., ECF 71-7 at 21, 23 (presenting “risk continuum” graph and photos of smokeless tobacco products used worldwide)). Yet Dr. Busse’s general causation opinion is “independent of” Skoal or Red Man. (Busse Dep. at 71:8–13.) In developing it, he did not separate moist snuff (Skoal) from loose leaf chewing tobacco (Red Man). (*Id.* at 180:21–181:2.) The result is an opinion that will not “help the trier of fact to understand the evidence or to determine a fact in issue” or constitute “scientific knowledge for purposes of the case.” *Fed. R. Evid.* 702(a); *Paoli*, 35 F.3d at 743 (emphasis in original); cf. *Soldo*, 244 F. Supp. 2d at 548 (explaining evidence about the “effect of allegedly ‘similar’ [products] on the body” does not fit because it is no “substitute for direct evidence about the [product] in question”).

For example, the Surgeon General report differentiated snuff from “chewing tobacco” and noted evidence the latter can increase **oral cancer** risk is “not so strong” and the “risks have yet to be quantified.” (ECF 71-2 at ¶ 3.) Additionally, the 1981 article focused on snuff products—not loose leaf chewing tobacco. See (Winn Art.). The relevant questions are whether Skoal moist snuff or Red Man loose leaf chewing tobacco can cause **tonsil cancer**, but Dr. Busse’s general causation opinion is not calibrated to the **cancer** risks posed by those particular products. His opinion is not “sufficiently tied to the facts of the case” to “aid the jury.” *Daubert*, 509 U.S. at 591, 113 S.Ct. 2786 (internal quotation omitted).

C

1

Dr. Chabner’s general causation opinion is not reliable either. In his report, he states there is “undeniable” evidence—recognized by international and national health organizations—that “smokeless tobacco products cause human **cancer**.” (Chabner Rpt., ECF 71-6 at 3.) He cites IARC’s determination that smokeless tobacco is “carcinogenic to humans” and causes “**oral cavity cancers**” and the Surgeon General’s conclusion that “smokeless tobacco can cause **cancer** and other non-cancerous oral conditions and can lead to nicotine addiction and dependence.” (*Id.*) He writes that, according to the CDC and AAO, smokeless tobacco contains “**cancer** causing [TSNAs] and multiple other substances identified as carcinogens.” (*Id.*) Finally, he asserts “[i]t has

been determined” that smokeless tobacco users “experience greater than 10 fold increases in the risk of [cancers of the mouth, gums, oropharynx](#), larynx, and salivary glands as compared to non-users of tobacco products,” and for these anatomical sites the [cancer](#) risk is equal to that experienced by a smoker “of up to 20 cigarettes a day.” (*Id.* at 3–4.)

[24] Like Dr. Busse, Dr. Chabner did not adequately consider the relevant literature. See *Zolof I*, 26 F. Supp. 3d at 460–61. Dr. Chabner also erroneously relied on the IARC and 1986 Surgeon General report. Further, a significant part of his “literature review” consisted of background reading in medical textbooks; in his expert report he cited to one paper, which he learned about from Hoefling’s lawyer. See (Chabner Dep. at 163:23–164:15, 165:8–11, 165:18–166:8). At his deposition, he clarified that the finding cited in his report that smokeless tobacco use multiplies by more than ten the [oropharyngeal cancer](#) risk actually applies only to mouth and [gum cancers](#). (*Id.* at 182:15–184:13.) Relying on a “selected subset of evidence without sufficient analysis of contrary evidence” is a “significant methodological weakness.” *Zolof I*, 26 F. Supp. 3d at 461 (noting “[c]herry-picking” is always a concern”).

*8 [25] Dr. Chabner’s general causation opinion also unduly relies on biological plausibility. Noting the IARC’s conclusion that smokeless tobacco is carcinogenic for head, neck, esophageal and [pancreatic cancers](#), Dr. Chabner explains “there’s a lot of structures on the way down that had to be exposed to the same material coming from the smokeless tobacco.” (Chabner Dep. at 81:23–82:4.) Dr. Chabner “assume[s] that the pharynx is exposed.” (*Id.* at 171:5–17.) He points to “general knowledge of people in my field that [smokeless tobacco] causes [oral cancer](#).” (*Id.* at 179:9–18 (emphasis added).) The “supporting assumption[s]” for Dr. Chabner’s general causation theory are not “sufficiently grounded in sound” reasoning and methodology to enable it “to clear the reliability hurdle.” *TMI*, 193 F.3d at 677 (explaining “[a]ssumption-based conclusions” that fail this test “can hardly be relied upon as ‘good science’”). More fundamentally, there is a dearth of research to support it. See *Zolof II*, 26 F. Supp. 3d at 475. Even if Dr. Chabner’s series of inferences is sensible according to biological principles, expert testimony is inadmissible under *Daubert* if “any step” in the expert’s analysis makes it unreliable. *Paoli*, 35 F.3d at 745. That is true here for multiple steps. Dr. Chabner’s reasoning and methodology are not “sufficiently reliable to allow” the jury to consider his opinions. *TMI*, 193 F.3d at 665.

Dr. Chabner acknowledges an absence of data to support the view that Red Man or Skoal can cause [tonsil cancer](#) in general. He notes [tonsil cancer](#) is “very rare.” (Chabner Dep. at 125:20–23.) Based on his review of epidemiological research, the number of cases is “much too small” to determine whether smokeless tobacco causes tonsil cancer—and the “clearest” data are available for [oral cancer](#). (*Id.* at 81:13–16, 125:4–19); see (*id.* at 84:6–7, 84:16–20 (explaining there are a “number of deficiencies or lack of data” identifying a causative link between smokeless tobacco and [oropharyngeal cancer](#) and noting the relevant research contains “surprisingly scanty” patient numbers)). It would require a “whole different level of approach to this issue to determine whether the nonsmoking, non-HPV [cancers of the tonsils](#) are related to smokeless tobacco.” (*Id.* at 84:7–10.)

Indeed, in an effort to explain just how weak the epidemiological evidence was, Dr. Chabner compared the evidence linking smokeless tobacco products to [oropharyngeal cancer](#) to an earlier study that found an association between [insulin](#) and [cancer](#). (Chabner Dep. at 86:6–87:9.) Both involved “small numbers of patients and incomplete data” that were “just not sufficient to draw conclusions about [carcinogenesis](#).” (*Id.* at 86:23–87:3.) He explained that without “a totally different kind of study,” it was “really impossible to draw any conclusions.” (*Id.* at 89:19–21.) His own experience cautions against drawing causal conclusions in the face of inconclusive epidemiological research: when a more robust study reexamined the link between [insulin](#) and [cancer](#), it demonstrated no causal association existed. (*Id.* at 21–24.) Ultimately, he agrees with U.S. Smokeless’ epidemiologist that the available data does not support the conclusion that smokeless tobacco causes [tonsil cancer](#). (*Id.* at 90:2–10, 174:13–14.)

This absence of supporting data renders unreliable Dr. Chabner’s view that Red Man and Skoal can cause [tonsil cancer](#) in general. See *Schneider*, 320 F.3d at 404. It does not “reliably follow from the facts known to [Dr. Chabner] and the methodology [he] used.” *Heller*, 167 F.3d at 153. Dr. Chabner’s general causation opinion also lacks a scientific foundation for largely the same reasons as Dr. Busse’s. See *Paoli*, 35 F.3d at 742 (explaining that *Daubert*’s reliability prong requires determining the “scientific validity” of scientific evidence).

Moreover, Dr. Chabner's general causation opinion does not fit the case. His report does not distinguish between types of smokeless tobacco. *See* (ECF 71-6 at 3–4). He concedes he is “not an expert” on smokeless tobacco-product details but acknowledges “the products are different.” (Chabner Dep. at 91:3–9.) It is “really hard to say, in a blanket way, that smokeless tobacco is all the same and that we can do a study that way.” (*Id.* at 91:12–14.) Nonetheless, he did not consider the 1986 Surgeon General report's statement differentiating chewing tobacco from moist snuff. (*Id.* at 178:22–179:8.)

*9 Dr. Chabner's opinion lacks “good grounds” given his failure to grapple with the differences between smokeless tobacco product types. *Paoli*, 35 F.3d at 743 (explaining *Daubert*'s “good grounds” standard applies to the part of an expert's analysis that “connects the work of the expert to the particular case”); *e.g.*, *Zolof I*, 26 F. Supp. 3d at 458–60 (rejecting the argument that it is proper for an expert to interpret data about a class of drugs to support the existence of a causal relationship between a drug in that class and birth defects).

D

Dr. Tomar's general causation opinion also does not fit the case. First, he opines using “moist snuff or loose leaf chewing tobacco” causes “cancer in humans.” (Tomar Rpt., ECF 70-3 at 5.) Dr. Tomar explained he reached this conclusion following “extensive reviews of the scientific evidence conducted by expert panels convened by” the Surgeon General and IARC. (*Id.* at 6.) Second, he maintains Skoal and Red Man contain “high levels of substances established as carcinogenic to humans.” (*Id.* at 5.) Dr. Tomar notes CDC and FDA analyses found “relatively high levels of TSNA” in Skoal and Red Man. (*Id.* at 6.) Third, he explains that while TSNA levels in Skoal “may have declined” in the 1980s, they have stayed “very high” compared to other types of smokeless tobacco and “changed little since at least the early 1990s”; and Red Man's TSNA levels “have not changed appreciably” dating to “at least the 1980s.” (*Id.* at 5.) Dr. Tomar explains early-1990s published research suggested levels of two TSNA, NNN and NNK, in leading U.S. moist snuff brands had declined since 1980 but a 2004 measure of those levels “suggests that nearly all varieties and flavors of [Skoal] had TSNA levels that were as high as or higher than had been reported a decade earlier.” (*Id.* at 6–7.) Dr. Tomar notes that in 2009 NNN and NNK levels “remained much higher in Skoal products than in other Altria-manufactured smokeless tobacco products.” (*Id.* at 7.) He also explains that while Red Man's TSNA levels are “lower than those reported” for Skoal, they have not “changed appreciably since at least the early 1980s” and have stayed “much higher than levels found in low-TSNA smokeless tobacco products.” (*Id.*)

[26] Dr. Tomar's report includes generic opinions about smokeless tobacco's carcinogenicity and TSNA content rather than an opinion directly applicable to the relevant question: whether Red Man and Skoal can cause tonsil cancer. *See Schneider*, 320 F.3d at 404 (describing Rule 702's fit requirement). His report's first opinion—using “moist snuff or loose leaf chewing tobacco” causes “cancer in humans”—is too broad to help the jury. (Tomar Rpt. at 5); *Daubert*, 509 U.S. at 591–92, 113 S.Ct. 2786. It makes no difference that Dr. Tomar based this conclusion on “extensive reviews” by experts because it lacks a “valid scientific connection to the pertinent inquiry” on general causation. (Tomar Rpt. at 6); *Daubert*, 509 U.S. at 591–92, 113 S.Ct. 2786. The same goes for his opinions about TSNA. Although they may be logically relevant in the evidentiary sense, they lack a specific connection to general causation here. *See Paoli*, 35 F.3d at 745 (stating the fit standard is “higher than bare relevance”); *Fed. R. Evid.* 401.

A different example underscores why Dr. Tomar's general causation opinions would not “assist the trier of fact.” *Schneider*, 320 F.3d at 404. He stated the 2016 Wyss study's “bottom-line conclusion” was consistent with the proposition that “the use of

smokeless tobacco [is] a carcinogen.” (Tomar Dep. at 200:11–14.) Even if true, it is only a small part of the picture. As Pinkerton expert Walter Lee noted, carcinogen exposure “by itself is not a guarantee of cancer formation.” (Lee Rpt., ECF 82-5 at 2.)

2

***10 [27]** Dr. Tomar's opinion on general causation is also unreliable. In connecting his generic opinions about the carcinogenicity of smokeless tobacco to tonsil cancer in particular, he resorts to biological plausibility, following the errant path taken by Drs. Busse and Chabner. He claims smokeless tobacco products have not been “established” as safe and that they “continue to have relatively high levels of known carcinogens,” among them TSNA—s—which “certainly would be consistent with there being an elevated risk” for tonsil cancer. (Tomar Dep. at 138:15–24.) He contends it is “hard to imagine a mechanism” through which there is an increased esophageal cancer risk from smokeless tobacco “without the carcinogens contacting the oropharynx.” (*Id.* at 185:20–23); *see also* (*id.* at 263:18–264:1 (explaining smokeless tobacco products are known carcinogens and “[b]iologically” it “wouldn't make sense” for the cancer risk to “stop[] right at the opening of the pharynx”)).

Dr. Tomar appears to have conducted a more thorough literature search than Drs. Busse and Chabner. *See* (Tomar Dep. at 101:20–23, 105:3–10, 106:11–16). But like his colleagues, he ultimately could not move past biological plausibility and identify data to support general causation. This failure was not due to neglect: Dr. Tomar admits that when a theory is biologically plausible, it requires support from epidemiological research. (*Id.* at 192:23–193:1.) He agrees a biological plausibility-based theory of general causation like his ordinarily “would be supported by” an investigation into particular anatomical sites, like the oropharynx, to identify supporting evidence. *See* (*id.* at 185:25–186:13).

[28] Yet the existing research falls short. A general causation expert must address “both supportive and contrary evidence” when forming an opinion. *Zolof II*, 26 F. Supp. 3d at 470 (explaining the impermissibility of ignoring “findings of those studies from which conclusions at odds with [the expert's] opinion were drawn”). A commentary on a 2002 article Dr. Tomar co-authored, while noting the article's limitations, stated “[i]nterestingly, chewing tobacco and moist tobacco were not associated with an increased cancer risk of the oral cavity, the oropharyngeal cavity, or the larynx.” (ECF 70-5 at 226 (emphasis added).) Dr. Tomar also reviewed the 2016 Wyss study, which he describes as the most “on point” for his work on this case, noting that “really small sample sizes” could make it difficult to draw meaningful conclusions from “site-specific estimates.” *See* (Tomar Dep. at 188:7–12, 199:7–9, 201:4–6); (*id.* at 264:2–5 (stating there is no “precise” estimate “specific to the tonsil” for the cancer risk of using smokeless tobacco products)). Notwithstanding this absence of data, Dr. Tomar estimates using smokeless tobacco at least “doubl[es]” oropharyngeal cancer risk. (*Id.* at 264:21–265:5.) He came to this guess by analogizing to the oral cavity. (*Id.* at 265:17–266:4.)

The biological plausibility and analogical reasoning Dr. Tomar used to form his view that Skoal or Red Man can cause tonsil cancer are not scientific “principles and methodology” that open the *Daubert* gate. 509 U.S. at 595, 113 S.Ct. 2786. Rather, they amount to “subjective belief or unsupported speculation.” *Id.* at 590, 113 S.Ct. 2786. His view is not “based on valid reasoning and reliable methodology.” *TMI*, 193 F.3d at 665 (internal quotation marks omitted). Moreover, Dr. Tomar's methods fail at least three of the Third Circuit's reliability factors. *Paoli*, 35 F.3d at 742 n.8. They amount to an “[un]test[ed]” hypothesis (or, alternatively, one not validated in the limited testing that has been done); there are no “standards controlling [their] operation”; and they bear precisely the wrong type of “relationship” to the most important “method[] which ha[s] been established to be reliable”: they are unmoored from epidemiological data. *Id.*; *see Zolof II*, 26 F. Supp. 3d at 475.

E

***11** Even if Hoefling's experts had reliably established general causation, the Court would exclude Drs. Busse's and Chabner's specific causation opinions. While both doctors purport to reach their conclusions based on a differential etiology of Hoefling's

tonsil cancer, (Busse Rpt. at 4; Chabner Dep. at 202:7), neither could rule out HPV as the cancer's cause, and they lack "good grounds" for believing smokeless tobacco use was the more likely cause. *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786.

[29] [30] Physicians may base their opinions on the cause of a person's illness on a properly performed differential etiology.⁵ See *Heller*, 167 F.3d at 154. When conducting such an analysis, the expert must "rule in" then "rule out" possible causes of the illness. *Zolof III*, 176 F. Supp. 3d at 494. Experts are not required to address all possible causes, but "[o]bvious alternative causes need to be ruled out." *Heller*, 167 F.3d at 156 (quoting Daniel J. Capra, *The Daubert Puzzle*, 32 Ga. L. Rev. 699, 728 (1998)).

[31] [32] Once a defendant points to a plausible alternative cause of the plaintiff's illness, the expert must "offer a good explanation as to why his or her conclusion remains reliable." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 808 (3d Cir. 1997). A physician need not perform every possible test to confirm his opinion, but he must "employ[] sufficient diagnostic techniques to have good grounds" for his conclusion. *Paoli*, 35 F.3d at 761.

1

[33] The first problem with Drs. Busse's and Chabner's differential etiologies is that they resisted "ruling in" tonsil cancer's predominant cause: HPV. HPV accounts for eighty percent of tonsil cancers. (Pinkerton SOMF ¶ 92.) Despite this statistic, both experts demanded affirmative evidence that Hoefling had an HPV infection before meaningfully considering it as a possible cause.

In his report, Dr. Busse explains he could not "rule ... in" HPV without a positive P-16 test.⁶ (Busse Rpt. at 4.) Dr. Chabner said he dismissed HPV as a possible cause because there was no "overwhelming evidence" Hoefling had the virus. (Chabner Dep. at 174:19–22.) Nothing short of "a wife with cervical cancer" or "a positive P-16" test would have led him to consider HPV as a cause. (*Id.* at 174:24–175:1.) This approach is flawed given both HPV's pervasiveness and the low probability it would have been detected before Hoefling's cancer diagnosis. As Dr. Busse explained, most men with HPV infections in the throat "would never know" they were infected. (Busse Dep. at 135:17–136:2.)

A proper differential etiology does not work like this. Differential etiology is a reliable technique because it requires doctors to demonstrate, through a process of elimination, that their hypothesized cause is more likely than alternative causes. *Paoli*, 35 F.3d at 758; *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 254 (3d Cir. 2008). The absence of a positive HPV test is not evidence HPV was absent. *Soldo*, 244 F. Supp. 2d at 521. It was improper to treat HPV as implausible simply because no conclusive test was performed. Doing so spared Drs. Busse and Chabner's preferred hypothesis from "the rigors of scientific testing," *Paoli*, 35 F.3d at 764, and undermined the reliability of their differential etiologies.

*12 Indeed, while Dr. Chabner claims to have performed a differential etiology, the process he describes does not involve methodically ruling out alternative causes. He "just came to the conclusion" that smokeless tobacco contributed to Hoefling's cancer after looking at what he considered the relevant risk factors. (Chabner Dep. at 202:10–19.) In doing so, he emphasized "there's no cookbook that can tell you exactly how to weigh [those factors] in individual patients." (*Id.* at 202:9–10.) While this holistic approach may be useful in medical practice, it is not a rigorous method for proving causation. See *In re Zolof (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 797 n.52 (3d Cir. 2017) ("[A] scientific method of weighting must be explained to prevent a 'conclusion-oriented selection process.'") (quoting *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002)).

2

The second problem with Drs. Busse's and Chabner's differential etiologies is that if HPV had been ruled in, it could not be reliably ruled out without a successful tumor biopsy. Both experts acknowledge a tumor biopsy could have determined whether Hoefling's [cancer](#) was HPV related. *See* (Busse Dep. at 62:4–5 (“the definitive tests ... would have been of the tonsil tissue itself.”)); (Chabner Dep. at 197:23–198:4, 204:4–205:5). But the [fine needle biopsy](#) of Hoefling's tumor was indeterminate, and his treating physician did not order additional testing. (Pinkerton SOMF ¶¶ 20–21.)

Given the difficulty of detecting HPV and the fact that it is the leading cause of [tonsil cancer](#), Drs. Busse and Chabner could not rule out HPV without this test. Busse admits that without more testing, “we really don't know if there was HPV or not.” (Busse Dep. at 61:22–24); *see also* (*id.* at 162:15–163:10). In his mind, there is “an equal probability” that HPV or smokeless tobacco caused the [cancer](#), but “unfortunately there's no way to know.” (*Id.* at 173:13–15.) Similarly, Dr. Chabner agrees “HPV is still one of those things that's out there that we cannot rule out.” (Chabner Dep. at 204:24–205:5); *see also* (*id.* at 136:20 (“HPV could be the cause. We don't know.”)).

As their concessions show, neither Busse nor Chabner dispute that a tissue biopsy is necessary to properly rule out HPV. In his own practice, Dr. Busse would have conducted some sort of biopsy to determine whether the [cancer](#) was HPV related. (Busse Dep. at 62:4–9, 63:10–64:7.) Without one, any differential etiology will be inconclusive. (*Id.* at 62:11–12 (“[T]he fact is we have two ... possible causes for why he developed [cancer](#).”).) Dr. Chabner agrees it is important to test [tonsil cancers](#) for HPV whenever possible. (Chabner Dep. at 48:9–49:5, ECF 76-12). To the extent Hoefling's experts defend the decision not to attempt another biopsy, they do so on pragmatic grounds: Hoefling's physician may have foregone further testing because Hoefling's *treatment* would have been the same regardless of his [cancer's](#) cause. (Busse Dep. at 67:22–68:6, ECF 76-8; Chabner Dep. at 204:15–23, ECF 71-4.) That may be true, but it does not diminish the importance of a biopsy for determining the *cause* of his [cancer](#).

3

In the absence of a conclusive tissue biopsy, Drs. Busse and Chabner turned to other heuristics to discount, if not rule out, HPV as a cause of Hoefling's [cancer](#). Because the standard method for ruling out HPV—a biopsy—was indeterminate, the experts needed to demonstrate that the alternative grounds for their conclusions were reliable. *See Zoloff, 858 F.3d at 797* (“[S]tandard techniques bolster the inference of reliability; nonstandard techniques need to be well-explained.”). They failed to do so. None of the reasons they offer for rejecting HPV—Hoefling's age, his sexual history, the opinion of his treating physician, the absence of an HPV diagnosis in his and his wife's medical records and his long history of smokeless tobacco use—were “good grounds” for ruling out the most frequent (by far) cause of [tonsil cancer](#).

*13 First, both physicians argue HPV was unlikely to be the cause of Hoefling's [cancer](#) because of his age. (Busse Dep. at 61:24–62:2, ECF 71-3; Chabner Rpt. at 4, ECF 71-6.) They point out HPV accounts for a higher proportion of [oropharyngeal cancers](#) among younger people. (Busse Dep. at 134:11–14.; Chabner Rpt. at 4.) But HPV accounting for a higher proportion of [oropharyngeal cancer](#) cases among younger people does not make it less likely to cause [cancer](#) in older people. It may be that other risk factors, like alcohol use or smoking, are less likely to cause [tonsil cancer](#) in younger patients, and that the incidence of HPV-related [cancers](#) is relatively constant. Indeed, one recent study found more than sixty-five percent of [oropharyngeal cancers](#) in those age seventy and over were HPV-positive. (Steinau Study at 824, ECF 71-13.)

When confronted with this data, Dr. Busse acknowledged HPV could not be ruled out based on Hoefling's age. (Busse Dep. at 162:11–14, 156:23–157:6.) Dr. Chabner similarly conceded that it has “never been a contention” that HPV does not cause [oropharyngeal cancer](#) in older people. (Chabner Dep. at 136:12–13.) He speculates that the incidence of HPV might be lower among eighty-year-olds than it was among seventy-year-olds, (*id.* at 136:18–24), but offers no supporting evidence. He merely suggests that because the rate of HPV-positive [cancers](#) was lower among those older than seventy than it was in younger cohorts, further disaggregated data might show the rate continues to decline at higher ages. But the seventy-plus HPV-positive cohort in the Steinau study ranged from seventy to ninety-two and the study contained no additional information about age distribution

within the cohort that might support Dr. Chabner's guess. (Steinau Study at 824.) Ultimately, neither expert cites evidence for why age was a "good ground" for ruling out HPV, and the Court is not required to take their word for it. *Zolof III*, 176 F. Supp. 3d at 495.

Second, Drs. Busse and Chabner cite Hoefling's sexual history as a reason to rule out HPV. Dr. Busse contends that Hoefling's "serial monogamy" put him at lower risk of HPV, (Busse Dep. at 61:24–62:4), while Dr. Chabner believes that because Hoefling never had oral sex, HPV was unlikely to have caused his cancer, (Chabner Dep. at 136:15–16.).

Record evidence, however, undercuts Busse and Chabner's reasoning. In addition to his four wives, Hoefling "had girlfriends" during the 1970s. (Hoefling Dep. at 110:6). While he considers only two of his non-marital relationships "significant," (*id.* 107:3–112:16), they were two among "many," (*id.* at 112:7). During his deposition, Dr. Busse acknowledged that if Hoefling had not been monogamous in his middle age, he would be at higher risk for HPV infection. (Busse Dep. at 197:12–17.) Even if Dr. Busse had pointed to studies showing that serial monogamy decreased the risk of HPV infection, which he did not, there is no basis for concluding that Hoefling had in fact been "serially monogamous."

Dr. Chabner's opinion is also unmoored from reality. He admits he never asked Hoefling whether he engaged in oral sex. (Chabner Dep. at 80:1–3.) He "got the impression" he had never had oral sex from his lawyer. (*Id.* at 80:12–16). As the Third Circuit explained in *In re Paoli Railroad Yard PCB Litigation*, "a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness." 35 F.3d at 762. Dr. Chabner did even less, basing a critical part of his analysis on nothing more than the assertions of plaintiffs' counsel.

More to the point, both experts agree HPV is prevalent and easily acquired. *See* (Busse Dep. at 218:7–10 (agreeing HPV is a "ubiquitous virus that most people contract")); (Chabner deposition 144:24–145:19 (explaining "there are a lot of ways of getting HPV" and "most people" have been exposed to HPV without knowing it)). And neither cite research to support their conclusion that Hoefling's lifestyle put him at particularly low HPV risk. Indeed, Dr. Chabner admits he is merely speculating. (Chabner Dep. at 145:14–16 ("I don't know. I'm not a sexual epidemiologist.")) An expert cannot eliminate alternative causes based on "subjective beliefs or unsupported speculation." *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003) (citation omitted).

*14 Third, both experts rely on the opinion of Hoefling's treating oncologist, who "doubted" HPV had caused his tonsil cancer, but did not explain why. (Busse Rpt. at 4; Chabner Rpt. at 4.) Faith in the wisdom of treating physicians "is not the stuff of science." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th Cir. 2015). Drs. Busse and Chabner offer no explanation for why they believe his doubt is reliable. They cannot rest on the *ipse dixit* of Hoefling's physician any more than they can on their own.

Fourth, Drs. Busse and Chabner suggest in their reports that HPV was less likely because neither Hoefling nor his wife had a reported history of HPV. (Busse Rpt. at 4, Chabner Rpt. at 4) But Dr. Busse explained HPV is unlikely to show up in a man's medical records. (Busse Dep. at 165:2–13, ECF 76-8.) And Margaret Hoefling's lack of a reported history of HPV could be because the appropriate testing was never performed or the virus was dormant, rather than because she and her husband did not have it. *See* (Busse Dep. at 165:19–167:4). There is no evidence either expert reviewed her complete medical records, *cf. Paoli*, 35 F.3d at 762, let alone that those records would support the conclusion that if Gus Hoefling had HPV, it would be evident from Margaret Hoefling's medical history. Busse and Chabner cannot simply assume Mrs. Hoefling's doctors would have detected HPV had it existed. *See C.W.*, 807 F.3d at 837; *Soldo*, 244 F. Supp. 2d at 521.

Fifth, to the extent either expert falls back on Hoefling's long history of using smokeless tobacco as a justification for ruling out HPV, their reasoning is "fatally circular." *Soldo*, 244 F. Supp. 2d at 519. Differential etiology would have no power to test a hypothesis if the allure of the hypothesis itself could justify ruling out obvious alternative explanations.

For their differential etiologies to be reliable, experts must use scientifically valid methodologies to rule out plausible alternative causes. *Zolof III* at 495; see also *Kannankeril*, 128 F.3d at 808. Drs. Busse and Chabner did not. In the absence of a successful tissue biopsy, the only reliable means for determining whether HPV caused the cancer, they offer guesses about the probability of an HPV infection that are unsupported by science, the record, or both. Both experts admit they cannot actually rule out HPV. (Busse Dep. 173:13–15; Chabner Dep. 204:24–205:5.) Even if smokeless tobacco were as likely as HPV to have caused Hoefling's cancer, their inconclusive differential etiology would not support the conclusion that tobacco was the more likely cause.⁷ (Busse Dep. at 62:20–63:1; Chabner Dep at 137:18–21). There is too great a gap between their analysis and that conclusion. See *Joiner*, 522 U.S. at 146, 118 S.Ct. 512.

III

*15 Pinkerton and U.S. Smokeless are entitled to summary judgment for two reasons. First, Hoefling has not produced admissible expert testimony on the issue of causation, a necessary element of his claims. Second, even if his experts' causation opinions were allowed, these opinions are inadequate to establish a jury question on medical causation under Pennsylvania law.

A

[34] Summary judgment is proper if the movant proves there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56(a)*. A fact is “material” if it may affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A “genuine dispute” exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* A mere scintilla of evidence supporting the nonmoving party, however, will not suffice. *Id.* at 252, 106 S.Ct. 2505. Rather, the nonmovant must “set forth specific facts showing that there is a genuine issue for trial.” *Id.* at 256, 106 S.Ct. 2505.

[35] At summary judgment, a court may consider any material in the record that may be admissible at trial. See *Fed. R. Civ. P. 56(c)*; *Pamintuan v. Nanticoke Mem'l Hosp.*, 192 F.3d 378, 387–88 & n.13 (3d Cir. 1999). In doing so, a court “must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor.” *Prowel v. Wise Bus. Forms*, 579 F.3d 285, 286 (3d Cir. 2009). But it need not credit “[u]nsupported assertions, conclusory allegations, or mere suspicions.” *Betts v. New Castle Youth Dev. Ctr.*, 621 F.3d 249, 252 (3d Cir. 2010). Nor may a court make credibility determinations or weigh the evidence. See *Parkell v. Danberg*, 833 F.3d 313, 323 (3d Cir. 2016).

[36] To succeed on any of his claims, Hoefling must prove the Defendants' products caused his cancer. See *Mellon v. Barre-Nat'l Drug Co.*, 431 Pa.Super. 175, 636 A.2d 187, 191 (1993) (“Proof of causation is a necessary element in a products liability action as well as in a negligence action.”). Expert testimony is generally required to prove causation of a medical condition. *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 252 (3d Cir. 2008); see also *Cohen v. Albert Einstein Med. Ctr.*, 405 Pa.Super. 392, 592 A.2d 720, 723 (1991) (explaining that expert testimony is necessary where the case's facts are beyond an ordinary layperson's knowledge). Because Drs. Busse's, Chabner's and Tomar's expert opinions are inadmissible, no genuine issues of fact with respect to causation remain for the jury. See *Paoli*, 35 F.3d at 785.

B

[37] [38] [39] Pinkerton and U.S. Smokeless would be entitled to summary judgment even if Hoefling's experts' causation opinions were admitted. Under Pennsylvania law, experts on medical causation must testify to “a reasonable degree of medical certainty.” *Paoli*, 35 F.3d at 750. This is not merely an evidentiary requirement; it forms part of the plaintiff's burden of proof.

Id. at 751. If a plaintiff lacks evidence to satisfy this standard, summary judgment is appropriate. *Id.* at 752; *see also Valido-Shade v. Wyeth LLC*, 57 F. Supp. 3d 457, 461 (E.D. Pa. 2014); *Eaddy v. Hamaty*, 694 A.2d 639, 642–43 (Pa. Super. Ct. 1997).

[40] [41] [42] Whether an expert satisfies this standard does not depend on “magic words.” *Commonwealth v. Spatz*, 562 Pa. 498, 756 A.2d 1139, 1160 (2000). Instead, the Court determines whether the expert’s testimony, taken as a whole, is based on “a reasonable degree of medical certainty rather than upon mere speculation.” *Vicari v. Spiegel*, 936 A.2d 503, 510 (Pa. Super. Ct. 2007) (quoting *Spatz*, 756 A.2d at 1160). Pennsylvania courts have long drawn a distinction between reasonable certainty and probabilistic guesswork. *See id.* at 511; *Kravinsky v. Glover*, 263 Pa. Super. 8, 396 A.2d 1349, 1356 (1979). Testimony that something was “more likely than not” the cause of the plaintiff’s injury is insufficient. *Griffin v. Univ. of Pittsburgh Med. Ctr.–Braddock Hosp.*, 950 A.2d 996, 1003 (Pa. Super. Ct. 2008). Similarly, an expert does not express the requisite certainty when he puts the odds in favor of his theory of causation at just above fifty-fifty. *See id.*; *Valido-Shade*, 57 F. Supp. 3d at 461.

*16 [43] Dr. Busse’s testimony clearly falls below this threshold. He believes there is “an equal probability” that either smokeless tobacco or HPV caused Hoefling’s cancer. (Busse Dep. at 173:13–15); *see also (id.* at 62:20–63:1). Indeed, he cannot say either was *likely* the cause of Hoefling’s cancer. (*Id.* at 172:9–12 (explaining “you really almost can’t speculate” about the most likely cause of Hoefling’s cancer)); *see also (id.* at 225:22–226:8 (“[I]t’s like you have ... six candidates on an election slate. You could win with twenty-one percent.”)).

Dr. Chabner’s testimony is similarly inadequate. At deposition, he continuously expressed his opinion on causation in terms of probability hovering near fifty percent. (Chabner Dep. 188:8–10, ECF 173-4 (“[I]f I had to put a percentage on it, greater to fifty percent chance that [smokeless tobacco] was a significant factor”)); (*id.* at 202:19–20 (“[T]he chances were greater than yes and no.”)); (*id.* at 137:18–21 (arguing the Steinau study suggested “at least a fifty-fifty chance, if not better, that it’s not HPV related”)). A reasonable degree of medical certainty requires more than a finding by a preponderance of the evidence. *See Griffin*, 950 A.2d at 1004 n.5. Dr. Chabner’s testimony closely tracks the more likely than not, fifty-one-to-forty-nine odds that courts have found insufficient to meet that higher standard. *Id.* at 1003–04, *Valido-Shade*, 57 F. Supp. 3d at 461.

IV

Because Gus Hoefling’s negligence and strict liability claims against Pinkerton and U.S. Smokeless cannot survive summary judgment, the Court also grants summary judgment on Margaret Hoefling’s loss of consortium claim. The viability of her claim depends on those of her husband. *See Marshall v. Zimmer, Inc.*, No. 18-3363, 2020 WL 5408209, at *9 (E.D. Pa. Sept. 9, 2020).

An appropriate Order follows.

All Citations

--- F.Supp.3d ----, 2021 WL 6051382, Prod.Liab.Rep. (CCH) P 21,310

Footnotes

- 1 Dr. Tomar’s expert report contains a specific causation opinion. (ECF 70-3 at 5, 7). Plaintiffs subsequently clarified, however, that they seek to have him testify only to general causation. (Pls. Resp. to Pinkerton Mot. to Excl. Tomar Ops., ECF 81 at 1; Pls. Resp. to U.S. Smokeless Mot. to Excl. Med. Caus. Exps., ECF 84 at 5.)
- 2 Dr. Busse is a radiation oncologist and associate professor at Harvard Medical School who holds an endowed chair at Massachusetts General Hospital. (Busse Rpt., ECF 71-5 at 1–2.) He has treated nearly 5,000 patients with head

and neck cancer. (*Id.* at 1.) Dr. Chabner is a Harvard Medical School professor and clinical director emeritus at the Massachusetts General Hospital Cancer Center. (Chabner Rpt., ECF 71-6 at 2.) He has written and edited a textbook on cancer chemotherapy and biological-response modifiers. (*Id.*) Dr. Tomar is a professor and associate dean at the University of Illinois at Chicago College of Dentistry. (Tomar Rpt., ECF 70-3 at 3.) He has consulted on smokeless tobacco issues for many agencies and organizations and served as a FDA smokeless tobacco expert. (*Id.* at 3–4.)

- 3 The deposition testimony Plaintiffs highlight from U.S. Smokeless expert Dr. Richmon does not indicate otherwise. (Pls.’ Resp. to U.S. Smokeless Mot. to Excl. Med. Caus. Exps., ECF 84 at 11–12.) The testimony is misleading in that the term “oral cancer” is used in a broader sense—as an “umbrella term” encompassing the oral cavity and oropharynx—than it is elsewhere in the record. *See* (Richmon Dep., ECF 84-5 at 18:2–20:15).
- 4 While Pinkerton emphasizes these criteria, *see* (Pinkerton Mem. in Supp. of Mot. to Exclude Tomar, ECF 70-1 at 13; Pinkerton Mem. in Supp. of Mot. to Exclude Busse and Chabner, ECF 71-1 at 17–18), Plaintiffs’ experts do not claim to rely on them. *Cf. Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 677 (M.D.N.C. 2003) (noting the expert whose causation testimony the court excluded stated the “scientific methodology that I use to assess causation is derived from the Bradford Hill Criteria” (internal quotation omitted)). Nor would it have been appropriate to apply them here: scientists are to do so only after an epidemiological association is demonstrated. *Id.* at 678 (explaining Hill used as the “starting point” of his analysis “ ‘an association between two variables’ that is ‘perfectly clear-cut and beyond what we would care to attribute to the play of chance’ ” (quoting Bradford Hill, *The Environment and Disease: Association or Causation*, 58 Proc. Royal Soc’y Med. 295, 295–300 (1965))). That has not happened in this case.
- 5 While this method is often referred to as “differential diagnosis,” differential etiology is the more precise term. A differential diagnosis is used to determine what condition a patient has; a differential etiology is used to deduce its cause. *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1194 n.5 (11th Cir. 2010).
- 6 P-16 is a protein associated with HPV-related cancers. (Busse Dep. at 61:16–20.)
- 7 Drs. Busse’s and Chabner’s reports cursorily suggest that even if smokeless tobacco was not “the” cause of Hoefling’s cancer, it was “a” significant contributing factor. (Busse Rpt. at 4; Chabner Rpt. at 4). This alternative theory, which was not explained in their reports or during their depositions, does not diminish the importance of a proper differential etiology. If Hoefling is proceeding on a theory of concurrent causation, he still needs expert testimony to show smokeless tobacco played *some* role in causing his cancer. *See Rost v. Ford Motor Co.*, 637 Pa. 625, 151 A.3d 1032, 1050 (2016). Hoefling’s experts provide no basis for an opinion that smokeless tobacco can contribute to an HPV-related cancer. Both agree HPV can cause tonsil cancer on its own. *See* (Chabner Dep. at 199:18–19 (“We know that [HPV] causes this cancer by itself.”)); (Busse Dep. 65:22–24). Dr. Busse believes HPV is a “separate causal pathway” for tonsil cancer and, if it were the cause of Hoefling’s cancer, it would be “the overriding determinant” of the outcome. (Busse Dep. 65:3–24; 29:22–30:2.) While Dr. Chabner holds out the possibility that smokeless tobacco could contribute to an HPV-related cancer, he cannot even guess about what role it would play. (Chabner Dep. at 197:23–198:24.) He merely remains “suspicious” that smokeless tobacco would be a contributing factor.

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NOT FOR PUBLICATION

United States District Court, D. New Jersey.

UNITED STATES of America, et al., EX REL. Jessica PENELOW and Christine Brancaccio, Plaintiffs,

v.

JANSSEN PRODUCTS, LP, Defendant.

Civil Action No. 12-7758 (ZNQ) (LHG)

I

Signed 01/10/2022

Attorneys and Law Firms

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MEMORANDUM OPINION

QURAISHI, District Judge

*1 This matter comes before the Court upon several motions to exclude opinions and testimony filed by Janssen Products, LP (“Janssen”), and Relators Jessica Penelow and Christine Brancaccio (collectively, “Relators”). The parties seek to exclude expert reports and testimony under the admissibility requirements of [Federal Rule of Evidence 702](#) and the principles espoused in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The Court has carefully considered the parties’ submissions and decides the matter without oral argument pursuant to [Federal Rule of Civil Procedure 78](#) and [Local Civil Rule 78.1](#). For the reasons set forth below, the parties’ motions to exclude expert testimony will be granted in part and denied in part.

I. BACKGROUND & PROCEDURAL HISTORY

On December 18, 2012, Relators¹ filed this action on behalf of the federal government, twenty-six states, and the District of Columbia (collectively, “Government Plaintiffs”) alleging fifty-six counts under the Federal False Claims Act (“FCA”), the Federal Anti-Kickback Statute (“AKS”), and the false claims acts of various states. (ECF No. 1.) The United States and certain States declined to intervene. (ECF Nos. 46, 48, 55.) On October 3, 2016, Johnson & Johnson (“J&J”) and Janssen filed Motions to Dismiss. (ECF Nos. 56, 57.) On May 31, 2017, the Court granted in part and denied in part Janssen’s motion but dismissed all claims against J&J. (ECF Nos. 86, 87.) Relators subsequently filed the Second Amended Complaint on June 30, 2017. (“Second Am. Compl.,” ECF No. 90.) On October 14, 2020, Janssen filed a Motion for Summary Judgment. (“Summary Judgment,” ECF No. 187.) Around the same time, Relators and Janssen filed several motions to exclude expert testimony and opinions. (ECF Nos. 179, 181, 183, 192, 194, 196, 198, 200, 202.) Thereafter, the Court stayed the matter to afford the parties the opportunity to attend private mediation, but the mediation was not successful. (ECF Nos. 233, 236.)

The claims in this action arise from Janssen’s purported kickback scheme and off-label (“OL”) promotion of two HIV/AIDS drugs: [Prezista](#) and Intelence. (Second Am. Compl. at 1–2.) With respect to [Prezista](#), Relators allege that Janssen, through its sales representatives and managers, delivered false and misleading messages to physicians by: (1) promoting [Prezista](#) as “lipid

neutral”; and (2) misstating [Prezista's](#) superiority, efficacy, and potency based on the uniqueness of its “binding affinity.” (*Id.* ¶¶ 2, 105.) Relators claim [Prezista](#) presents a serious risk of [cardiovascular disease](#) because [Prezista](#) increases lipids, such as cholesterol and [triglycerides](#). (*Id.* ¶¶ 3–4, 106–08.) They allege Janssen misrepresented that [Prezista](#) “would not affect or increase a patient's cholesterol or [triglyceride](#) levels, which is directly contradicted by the FDA-approved label for [Prezista](#).” (*Id.* ¶¶ 3, 106.) Relators also allege Janssen misrepresented [Prezista](#) as having superior “binding affinity,” which prevents HIV from mutating and becoming resistant. (*Id.* ¶¶ 6, 126.) Furthermore, Relators contend Janssen's representations about [Prezista's](#) superior binding affinity were based on a clinical study that was of limited scientific value and was not included in the drug's FDA-approved labeling. (*Id.*) Relators allege numerous instances where Janssen sales representatives and managers misrepresented [Prezista's](#) effect on lipids and its superior binding affinity. (*Id.* ¶¶ 124–25, 137, 183.) The OL promotion concerning [Prezista](#) as a lipid-neutral drug began in 2006 and continued through approximately 2014, and the OL promotion concerning its superior “binding affinity” began around 2007 and continues through present. (*Id.* ¶¶ 4–5, 106, 126.)

*2 As for Intelence, Relators allege that Janssen, through its sales representatives and managers, provided false and misleading statements to physicians by marketing the drug as safe and effective for: (1) once-daily dosage; and (2) safe and effective for “treatment-naïve patients,” which refers to patients who have never taken any antiretroviral medication. (*Id.* ¶ 9.) Relators allege Janssen promoted Intelence for once-daily dosing, contrary to its FDA-approved label specifying twice-daily dosing. (*Id.* ¶ 10.) This is significant because “if a patient does not carefully follow the FDA-indicated dosing drug regimen, their [HIV viral load](#) can increase, potentially weakening the drug's ability to fight the disease.” (*Id.*) In addition, Relators allege that Intelence was “only indicated for treatment-experienced patients,” not treatment-naïve patients. (*Id.* ¶ 11.) Prescribing Intelence to treatment-naïve patients is harmful because it could prematurely “cause [them] to run out of drug options as their diseases progresses.” (*Id.* ¶ 12.) Relators allege numerous instances where Janssen sales representatives and managers engaged in OL promotion concerning Intelence “from the time of its launch in 2008, continuing through September 2014.” (*Id.* ¶¶ 150, 154, 159.)

Relators allege that Janssen's OL “marketing of [Prezista](#) and Intelence was widespread.” (*Id.* ¶¶ 13, 160.) According to Relators, Janssen instructed its national sales force to market the drugs OL during pod calls, district calls, district meetings, trial meetings, and plan of action meetings. (*Id.* ¶¶ 161–78.) During these calls and meetings, upper management and district managers encouraged OL marketing, and sales representatives from different districts to share sales strategies and tips about marketing Intelence and [Prezista](#) OL. (*Id.* ¶¶ 162–64.) As a result, Janssen representatives engaged in OL marketing during sales calls with physicians, dinner programs, and Speaker Programs. (*Id.* ¶¶ 13, 179–205.) In addition, Relators claim the Speaker Programs amounted to kickbacks in violation of the AKS because Janssen paid speakers at the dinner programs. (*Id.* ¶¶ 13, 71.) According to Relators, the physician-speakers were paid an increasing honorarium based on the number of prescriptions they wrote and their market share of the drugs, which Janssen calculated by determining the percentage of Janssen drugs a doctor prescribed as compared to non-Janssen drugs in the same class. (*Id.*)

Relators allege that Janssen knowingly and misleadingly influenced physicians' medical judgments through its OL promotion of [Prezista](#) and Intelence. (*Id.* ¶ 15.) Moreover, they allege Janssen knew the Government Plaintiffs reimbursed a substantial portion of [Prezista](#) and Intelence prescriptions. (*Id.* ¶ 16.) Because a significant percentage of HIV/AIDS patients are enrolled in Medicaid and Medicare, Janssen allegedly caused claims tainted by the OL marketing and kickback schemes to be submitted to the Government Plaintiffs for reimbursement. (*Id.*)

II. LEGAL STANDARD

[Federal Rule of Evidence 702](#) governs the admissibility of expert testimony and provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. “Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualification, reliability, and fit.” *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80 (3d Cir. 2017) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). The party offering the expert testimony bears the burden of establishing the existence of each factor by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), amended by 199 F.3d 158 (3d Cir. 2000).

The Third Circuit has “interpreted Rule 702’s qualification requirement liberally.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (citing *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)). A “broad range of knowledge, skills, and training qualify an expert as such.” *Paoli*, 35 F.3d at 741. Because both the “substantive” and “formal” qualifications of an expert are viewed liberally, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” *Id.* Therefore, “[i]f the expert meets [the] liberal minimum qualifications, then the level of the expert’s expertise goes to credibility and weight, not admissibility.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997) (citation omitted). “[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate.” *Pineda*, 520 F.3d at 244 (alteration in original) (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)). However, while “background, education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions.” *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003).

*3 As for the “reliability” requirement, the Third Circuit has interpreted reliability “to mean that an expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” *Pineda*, 520 F.3d at 244 (internal quotations omitted) (quoting *Paoli*, 35 F.3d at 742). Rule 702 imposes a “gatekeeping” obligation on the trial court to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert*, 509 U.S. at 598; see also *Kumho Tires Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (gatekeeping obligation “applies to all expert testimony”). The purported expert’s testimony “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’; the expert must have ‘good grounds’ for his [or] her belief.” *Schneider*, 320 F.3d at 404 (citation omitted). Admissibility turns “on the expert’s methods and reasoning; credibility decisions arise after admissibility has been determined.” *Kannankeril*, 128 F.3d at 806. “The evidentiary requirement of reliability is lower than the merits standard of correctness.” *Paoli*, 35 F.3d at 744.

To satisfy the “fit” requirement, “the expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Schneider*, 320 F.3d at 404. The expert testimony meets the “fit” requirement when it “help[s] the trier of fact to understand the evidence or to determine a fact in issue...” Fed. R. Evid. 702. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591 (citation omitted). “Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Id.* at 591–92. The Third Circuit has also instructed that:

A judge frequently should find an expert’s methodology helpful even when the judge thinks that the expert’s technique has flaws sufficient to render the conclusions inaccurate. He or she will often still

believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct

Paoli, 35 F.3d at 744–45. See *Heller v. Shaw Indus. Inc.*, 167 F.3d 146, 152–53 (3d Cir. 1999) (finding the trial court should admit expert testimony “if there are ‘good grounds’ for the expert's conclusion” even if the court believes “there are better grounds for some alternative conclusion”).

Notably, the court also “must ensure that an expert does not testify as to the governing law of the case.” *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). In *Berkeley*, the Third Circuit explained that “the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties.” *Id.* at 218. “Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that ‘embraces an ultimate issue to be decided by the trier of fact,’ an expert witness is prohibited from rendering a legal opinion.” *Id.* at 217 (quoting *United States v. Leo*, 941 F.2d 181, 195–96 (3d Cir. 1991)).

III. DISCUSSION

Janssen moves to exclude certain opinions and testimony of the following experts: James T. O'Reilly, George P. Sillup, Kenneth W. Schafermeyer, Aaron E. Glatt, Virginia B. Evans, Israel Shaked, and Ian Dew. (ECF Nos. 192, 194, 196, 198, 200, 202.) Relators move to exclude certain opinions and testimony of the following rebuttal experts: Jon Smollen, Anupam Jena, and Eric S. Rosenberg. (ECF Nos. 179, 181, 183.) The Court addresses each expert in turn.

A. Janssen's Motion to Exclude the Testimony of James T. O'Reilly

Janssen filed a motion to exclude the expert report and testimony of James T. O'Reilly, (“O'Reilly Motion,” ECF No. 192), along with a brief in support of the Motion, (“O'Reilly Moving Br.,” ECF No. 192-1). Relators opposed the Motion, (“O'Reilly Opp'n Br.,” ECF No. 282), to which Janssen replied (“O'Reilly Reply,” ECF No. 251). Relators identified O'Reilly as an expert in FDA law, regulatory issues under the FCA, and government reimbursement. (Chuderewicz Decl., Ex. A, ECF No. 194-3.)

*4 According to Janssen, the problematic nature of O'Reilly's expected testimony becomes evident as early as the third paragraph of his opinion, where he summarizes his conclusion:

In my opinion, based on the evidence and my education and professional experience, Janssen misbranded *Prezista* and Intelence and engaged in off[-]label marketing of the drugs that was contrary to their FDA-approved labels, and, thus, the claims submitted to the government healthcare programs for these drugs were false because they were ineligible for reimbursement. Further, this conduct was material to the government's payment decision for reimbursement of claims for *Prezista* and Intelence.

(Chuderewicz Decl., Ex. A, “O'Reilly Report” ¶ 3, ECF No. 263.) Janssen counts three legal conclusions in that statement alone. (O'Reilly Moving Brief at 1, 4.) Beyond these concerns as to potentially improper legal advocacy, Janssen challenges O'Reilly's opinions on the grounds that they believe “he is not qualified to offer any non-legal opinions about the marketing of Intelence and *Prezista* or about government reimbursement for Intelence and *Prezista* prescriptions,” and Janssen contends “he does not tie any non-legal opinions to reliable principles or methods.” (O'Reilly Moving Br. at 2–10.)

In opposition, Relators maintain that O'Reilly does possess the necessary qualifications and that his opinions are reliable. (O'Reilly Opp'n Br. at 2.) Relators argue that O'Reilly's opinions “are grounded in well-supported citations to relevant

authority.” (*Id.* at 11.) His “report meets [the good grounds] standard and contains detailed citations to the relevant statutes, regulations, guidelines, policy documents, etc. relevant to his opinions regarding the government regulatory scheme at issue in this case.” (*Id.*) They note that O'Reilly has the educational, academic, and industry background to explain FDA and Centers for Medicare & Medicaid Services (“CMS”) regulatory issues. (*Id.* at 10.) In addition, with respect to Janssen's argument that O'Reilly provided a legal opinion, Relators fault Janssen for focusing on O'Reilly's conclusion while ignoring the rest of his opinion that explains the complex regulatory environment at issue in this case. (*Id.* at 12.) They cite instances where other courts have allowed experts to opine about the complex Medicare regulatory scheme. (*Id.* at 13.) Relators have their own view of what constitutes inadmissible legal conclusions: they insist that O'Reilly's opinions are proper because “they do not go to the ultimate issue to be decided by the jury in the case,” *i.e.*, whether Janssen is liable. (*Id.* at 15.) Relators temper their position by proposing that the Court defer assessing the admissibility of O'Reilly's potentially legal testimony until trial when there is more context and after hearing Janssen's objections. (*Id.* at 15 n.1.)

In its reply, Janssen focuses on O'Reilly's testimony regarding intent, stating that it is inadmissible legal advocacy. (*Id.* at 4.) Janssen emphasizes that “O'Reilly intends to instruct the jury on what the law requires and to tell the jury that Janssen violated the law.” (O'Reilly Reply at 1.) It argues that “[i]nstructing the jury on what the law requires is exclusively within the province of this Court.” (*Id.* at 3.) Furthermore, Janssen argues that O'Reilly is not qualified to reliably opine on matters because his experience is unrelated to the opinion he intends to offer. (*Id.* at 6–7.)

*5 The Court has reviewed O'Reilly's qualifications. He has advised on over-the-counter drug, pharmaceutical, and medical device issues, taught an FDA course as an adjunct law professor for twenty-five years, and currently chairs the FDA committee of the American Bar Association (“ABA”). (O'Reilly Report ¶ 7.) He teaches medical and public health for graduate students at the University of Cincinnati, College of Medicine, and he has authored over 50 textbooks and 220 articles. (*Id.* ¶ 5; *see also Id.* ¶¶ 4–9.) He has also authored the drugs chapter of the special textbook on AIDS for the ABA's Coordinating Committee on AIDS. (*Id.* ¶ 8.) O'Reilly can be reasonably characterized as a lawyer with a specialization in healthcare public policy. (*Id.* at 41–49.) Thus, based on his education and experience, the Court finds that O'Reilly satisfies the liberal minimum qualifications required for expert testimony admissibility. *Paoli*, 35 F.3d at 741. He is, therefore, qualified to speak on general topics concerning FDA regulations and reimbursement. Likewise, his experience is sufficient to render his testimony “reliable.” *Pineda*, 520 F.3d at 244

Notwithstanding his qualifications, the question of “fit” remains. The Court must determine whether O'Reilly's testimony will help the trier of fact. *Berkeley*, 455 F.3d at 217. This determination necessarily includes ensuring that he will not provide improper legal opinions that will intrude on the Court's role in explaining the law to the jury. *Berkeley*, 455 F.3d at 218. Although experts can testify about business customs and background information that they have developed through their personal experience and expertise, they cannot give opinions “as to what was required under the law, or whether the defendant complied with the [law].” *Id.* (quoting *Leo*, 941 F.2d at 196–97); *see also Casper v. SMG*, 389 F. Supp. 2d 618, 621 (D.N.J. 2005)). In *Berkeley*, the Third Circuit confirmed that an expert, a former SEC lawyer with experience in the crucial matter in the case, could testify about customs and business practices in the securities industry at the time the parties entered into their contested agreement. 455 F.3d at 218. However, the Third Circuit reversed the district court's decision to permit the expert to testify regarding the defendant's compliance with legal duties that arose under the federal securities laws because such testimony represented improper legal opinions. *Id.*

As a first matter, and consistent with *Berkeley*, the Court rejects Relators' proposed “ultimate issue” test for the admissibility of the portions of O'Reilly's testimony that verge on legal opinion. 455 F.3d at 217. “Ultimate issue” is inconsistent with the *rules of evidence*. Rule 704 expressly states that “[a]n opinion is not objectionable just because it embraces an ultimate issue.” The correct question in this context is whether, and to what extent, O'Reilly's opinion attempts to introduce improper legal testimony.

The Court has reviewed O'Reilly's report and finds acceptable those portions that provide background information regarding the drug approval process, misbranding in general, and the mechanism by which the government reimburses for prescriptions. Such background information could be helpful to the jury. Likewise, O'Reilly's observations regarding Janssen's compliance efforts could also prove helpful. Unfortunately, however, his report quickly devolves into his opinion as to legal issues. These include

but are not limited to: how Janssen's activities constituted OL promotion and therefore misbranding, (O'Reilly Rep. ¶¶ 29–34, 47–49); Janssen's purportedly purposeful manipulation of Medical Information Requests, (*id.* ¶¶ 40, 42); how Janssen's OL promotion can form the basis for a violation of the FCA, (*id.* ¶¶ 61–62, 70); and the legal test for materiality and its application, (*id.* ¶¶ 71, 73, 84–85). Because these portions of the O'Reilly report, and others like them, risk usurping the Court's primary role in articulating the law to the jury, the Court will exclude them. Under the circumstances, Relators' proposal that the Court defer its decision as to admissibility until trial is unsatisfactory. There are likely to be close cases requiring an admissibility determination at trial, but permitting O'Reilly to testify, in the first instance, as to what are clearly legal opinions would be prejudicial to Janssen. For these reasons, Janssen's motion to exclude the testimony of James T. O'Reilly will be granted in part and denied in part.

B. Janssen's Motion to Exclude Certain Opinions of George P. Sillup

*6 Janssen filed a motion to exclude the testimony of George P. Sillup, ("Sillup Motion," ECF No. 194), along with a brief in support of the Motion, ("Sillup Moving Br.," ECF No. 194-1). Relators opposed the Motion, ("Sillup Opp'n Br.," ECF No. 284), to which Janssen replied, ("Reply," ECF No. 249). Relators identified Sillup as an expert in pharmaceutical marketing issues relating to Janssen's marketing of [Prezista](#) and Intelence, and its Speaker Programs. (Chuderewicz Decl., Ex. A, ECF No. 194-3; Sillup Opp'n Br. at 4.) Sillup's report provides the following summary of the opinion he intends to offer at trial:

In my professional opinion and based on my understanding of the impact of pharmaceutical marketing and my review of the evidentiary record, I believe that Janssen's widespread and top-down campaign of off-label marketing for [Prezista](#) and Intelence was a substantial factor in driving the volume of OL prescribing for [Prezista](#) and Intelence.

(Chuderewicz Decl., Ex. B, "Sillup Report" at 8, ECF No. 264.) Sillup organized his report in two sections: (1) Janssen's management took multiple actions to facilitate or encourage OL marketing ("Marketing Opinion"), and (2) the increased numbers of OL scripts were the foreseeable and intended result of Janssen's OL marketing ("Causation Opinion"). (*Id.* ¶¶ 36–134).

Janssen argues that Sillup's Marketing and Causation Opinions are inadmissible because he does not tie the opinions to any reliable principles and methods. (Sillup Moving Br. at 2, 7.) Janssen also contends that Sillup's Causation Opinion is inadmissible because "he is not qualified to offer it" and the opinion "is an impermissible legal opinion." (*Id.* at 4–7.)

In opposition, Relators argue that "Sillup is qualified to offer all of his opinions, and his opinions are reliable." (Sillup Opp'n Br. at 8.) Relators explain that, in analyzing and evaluating Janssen's marketing conduct, Sillup "reviewed extensive evidence in the case and broke down his conclusions into multiple prongs that a jury can readily follow and assess." (*Id.* at 12.) He analyzed highly technical documents, such as the FDA-approved labels for [Prezista](#) and Intelence, the eligible patient population, and Janssen's sales forecasts. (*Id.* at 12.) Relators also argue that Sillup's opinion concerning causation "is both within [his] expertise and reliably based on his experience in pharmaceutical marketing, from both the academic and industry perspectives." (*Id.* at 20.) They note that Sillup has the educational, academic, and industry background to explain the marketing surveys Janssen commissioned. (*Id.* at 22.) In addition, with respect to Janssen's argument that Sillup provided a legal opinion, Relators argue that courts have allowed pharmaceutical marketing experts to opine about OL marketing campaigns as a "significant contributing factor" to OL sales. (*Id.* at 22–23.) In the alternative, Relators contend the phrase "substantial factor," the term Sillup used in his report, is a common phrase such that "its use does not take [his] expert opinions into the realm of legal conclusions." (*Id.* at 23.)

In its reply, Janssen reiterates that Sillup's Marketing Opinion "usurps the role of the jury and is untethered from reliable principles and methods." (Sillup Reply at 2–4.) Janssen likewise reiterates that "Sillup's Causation Opinion is inadmissible

because it impinges on the role of the jury, ... he is unqualified to opine on what caused doctors to prescribe HIV medications for HIV patients, ... [and] he fails to apply reliable causation methodology.” (*Id.* at 5–8.)

Sillup is a Professor in the Pharmaceutical & Healthcare Marketing Department at St. Joseph's University and served as chair of the Department from 2010 through 2017. (Sillup Report ¶¶ 4, 5; Sillup Report at 79.) Sillup holds an M.S. in Human Behavior and Development and a Ph.D. in Human and Organizational Structures. (Sillup Report ¶ 6; Sillup Report at 78.) He teaches courses on pharmaceutical marketing, publishes on the topic, and provides marketing consulting for pharmaceutical companies. (Sillup Report ¶ 5.) His research focuses on strategic planning, forecasting, market practices of pharmaceutical companies, and the effects of those practices on prescription medications. (*Id.*) Notably, he “transitioned to academia full time in 2004 after working 28 years in the pharmaceutical, diagnostic and medical device industry.” (*Id.* ¶ 4.) While working in the pharmaceutical industry, he held positions from salesman to Chief Operating Officer and “guided numerous product launches for drugs and devices, which included developing product forecasts, marketing materials and sales training program to support products” across the United States and global market. (*Id.*) The Court finds that Sillup's qualifications are substantial.

*7 According to Sillup, Relators retained him to opine on the following issues: (1) how pharmaceutical manufacturers promote the sale and use of drugs, especially when there are competing drugs in the market; (2) whether Janssen's management facilitated or encouraged the OL marketing done by its sales force and the paid speakers; and (3) whether Janssen's OL promotion and conduct a significant contributing factor in causing physicians to prescribe *Prezista* and *Intelence* for OL uses. (*Id.* ¶¶ 8–9.) In reaching his Marketing and Causation Opinions, Sillup assessed Janssen's strategic corporate documents, financial records, testimony, and relevant academic research. (*Id.* at ¶¶ 5; Sillup Report, at 94–102.)

As to whether Sillup used reliable principles and methods to reach opinions, the Court finds *Smith v. Pfizer*, 714 F. Supp. 2d 845 (M.D. Tenn. 2010), persuasive. In that case, the court denied the defendants’ motion to exclude testimony of a marketing expert who also concluded that the defendants’ OL marketing campaign led to an increase in OL prescriptions. *Id.* at 855. The defendants argued that he employed no ascertainable methodology. *Id.* However, the court found his testimony reliable because he “relie[d] on and frequently cite[d] scholarly articles and studies,” applied his “understanding of the drug marketplace and how marketing campaigns generally influence doctors,” and examined sales and data. *Id.* at 857. See also Fed. R. Evid. 702 Advisory Committee Notes to 2000 Amendments (explaining that when an expert witness relies primarily on experience rather than a scientific study, the expert must “explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts”); *United States v. Ford*, 481 F.3d 215, 219 (3d Cir. 2007) (reliability may turn on the proposed expert's “personal knowledge or experience”).

Here, like the expert in *Smith*, Sillup reviewed extensive evidence and broke down his conclusions into multiple prongs. (Sillup Report ¶¶ 5, 18–49; Sillup Report, Ex. A, at 94–102.) In his report, Sillup explained that Janssen's management took the following actions to facilitate or encourage OL marketing: (1) developed unrealistic sales forecasts before it launched *Prezista* and *Intelence*; (2) instructed and trained its national sales force to promote *Prezista* and *Intelence* for OL uses; (3) encouraged physicians to write OL scripts through the Speaker Programs where OL promotion took place; (4) set compensation policies for sales staff that was based on an expectation of OL marketing; (5) encouraged sales staff to use unapproved studies when promoting *Prezista* and *Intelence*; and (6) failed to discipline its sales staff or managers for OL marketing. (Sillup Report ¶¶ 18–49.) Indeed, Sillup reached these conclusions by analyzing the FDA-approved labels for *Prezista* and *Intelence*, the eligible patient population, and Janssen's sales forecasts. (*Id.* ¶ 12.) His report explained the highly technical process of creating sales forecasts for pharmaceutical products, and he relied on this same process to determine that Janssen created unrealistic sales forecasts for *Prezista* and *Intelence*. (*Id.* ¶¶ 18–28.) Sillup also analyzed documents tracking *Prezista* and *Intelence* sales to show that a significant proportion of sales were OL. (*Id.* ¶¶ 32–34.) Throughout his report, he referenced documents and testimony to show that Janssen's training of its sales force, its bonus incentive, and corporate culture all encouraged OL marketing. (*Id.* ¶¶ 34–49.) To the extent Janssen disagrees with the evidence and testimony Sillup relies upon to render his expert opinions, disagreement about his assumptions “go[] to the weight given to his testimony, rather than [its] admissibility.” *Leonard v. Stemtech Int'l Inc.*, 834 F.3d 376, 391 (3d Cir. 2016). See also *Breidor v. Sears, Roebuck & Co.*, 722 F.2d 1134, 1138–139 (3d Cir. 1983) (“Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to

be determined by the jury, not the trial judge.”); *Fed. R. Evid.* 702 Advisory Committee Notes to 2000 Amendments. Similarly, for the reasons stated above, this Court finds that Sillup used reliable principles and methods to reach his Marketing Opinion.

*8 In the causation portion of his report, Sillup concludes that the increased numbers of OL scripts of *Prezista* and *Intelence* were the foreseeable and intended result of Janssen's OL marketing. (Sillup Report ¶ 45.) First, the Court finds that Sillup is qualified to offer his opinion based on the specialized knowledge he has acquired through his many years of training, education, and experience. *Calhoun*, 350 F.3d at 322. Not only is he a professor in pharmaceutical marketing, but he worked in the pharmaceutical industry for nearly three decades and developed product sales forecasts, marketing materials, and sales training programs for new drugs. (Sillup Report ¶ 6.) In addition, his research focuses on strategic planning, sales forecasting, market practices of pharmaceutical companies, and the impact of those practices on prescription medications. (*Id.*)

Second, as to the reliability of Sillup's Causation Opinion, the Court notes that he relied on the following: (1) guidance from courts, federal agencies, and the Office of the Inspector General that recognize OL marketing can cause physicians to write OL scripts; (2) academic and marketing literature that shows OL marketing influences prescribers; and (3) Janssen's internal and external marketing surveys showing that its OL marketing was causing physicians to write OL scripts. (*Id.* ¶¶ 49–66.) The Court, therefore, finds that Sillup's opinion concerning causation is tied to reliable methods and principles. *See Smith*, 714 F. Supp. 2d at 857.

Third, courts have allowed experts to opine as to the causal link between pharmaceutical OL marketing efforts and doctors' prescribing decisions. *See, e.g., Smith*, 714 F. Supp. 2d at 856; *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1039–40 (C.D. Cal. 2016); *Hanrahan v. Wyeth, Inc.*, Civ. No. 04-1255, 2012 WL 2395986, at *5 (E.D. Mo. June 25, 2012). Accordingly, the Court will deny Janssen's motion to exclude the expert report and testimony of George P. Sillup.

C. Janssen's Motion to Exclude Certain Opinions of Kenneth W. Schafermeyer

Janssen filed a motion to limit the testimony of Kenneth W. Schafermeyer, (“Schafermeyer Motion,” ECF No. 196), along with a brief in support of the Schafermeyer Motion, (“Schafermeyer Moving Br.,” ECF No. 196-1). Relators opposed the Motion, (“Schafermeyer Opp'n Br.,” ECF No. 282), to which Janssen replied (“Schafermeyer Reply,” ECF No. 247). Relators identified Schafermeyer as a rebuttal expert to Janssen's expert, Dr. Babette Edgar, who intends to testify about the statutory and regulatory framework for Medicare Part D (“Part D”). (Chuderewicz Decl., Ex. A, “Schafermeyer Report” ¶ 3, ECF No. 265.)

Schafermeyer's report provides the following summary of the opinion he intends to offer at trial: “It is my opinion that CMS does maintain a ‘medically necessary and reasonable’ requirement for services under Part D and, based on Dr. Glatt's opinion, that prescriptions relying on Janssen's false and misleading marketing do not meet this standard and should not be covered.” (Schafermeyer Report ¶ 59.) Schafermeyer organized his report in two sections: (1) issues pertaining to Part D, including administration of the drug benefit, funding sources, drug coverage, and utilization management tools; and (2) the financial implications of Janssen's alleged behavior on Part D for promoting *Prezista* and *Intelence* for OL and/or medically unnecessary use (the “Coverage and Reimbursement Opinions”). (*Id.* ¶¶ 6–58.)

Janssen contends that Schafermeyer's Coverage and Reimbursement Opinions are inadmissible because he “does not have [the] relevant expertise to offer these Opinions.” (Schafermeyer Moving Br. at 3.) Although “Schafermeyer's experience may be sufficient for him to walk the jury through the Medicare Part D statutory framework, he has no expertise to opine on how CMS makes coverage and reimbursement decisions for antiretroviral medications under Medicare Part D.” (*Id.* at 1.) Janssen notes that Schafermeyer has not worked or consulted for CMS or a Part D sponsor, has not specifically taught about such topics, and has reimbursement knowledge that is not at issue here. (*Id.* at 2–4.) Janssen argues that Schafermeyer's Coverage and Reimbursement Opinions are based *solely* on his understanding of the regulatory framework and of CMS' factors in making coverage and reimbursement decisions. (*Id.* at 4.) Janssen concludes that Schafermeyer's education and experience do not “qualify him to testify on the more specific subject of how CMS makes coverage and reimbursement decisions under Medicare Part D for antiretroviral medications such as *Prezista* and *Intelence*.” (*Id.* at 4.)

*9 In opposition, Relators argue that Janssen overstated the qualification requirement for expert testimony admission. (Schafermeyer Opp'n Br. at 3, 11.) Noting that precedents show that "rejection of expert testimony is the exception rather than the rule," Relators state that "the liberal standards for admissibility have supported acceptance of expert[s'] opinions outside their narrow area of expertise in many different settings, including with regard to regulatory schemes." (*Id.* at 3–5.) To disprove Janssen's argument that Schafermeyer's Coverage and Reimbursement Opinions are based *solely* on his understanding, Relators point to Schafermeyer's basis for understanding the topic, including materials that Dr. Babette Edgar (Janssen's own expert) uses in her report. (*Id.* at 8–10.) Relators further argue that Janssen's arguments regarding Schafermeyer's lack of experience working or consulting for CMS go to the weight of his testimony, not its admissibility. (*Id.* at 11–12.)

In its reply, Janssen emphasizes four points to prove that "none of [Schafermeyer's] experience is relevant to his Coverage and Reimbursement Opinions." (Reply at 1.) According to Janssen, Schafermeyer does not explain which courses involved teaching Part D, how his teaching history relates to his Coverage and Reimbursement Opinions, or whether his courses taught Part D policy issues in great depth. (*Id.* at 3–4.) Janssen notes that Schafermeyer has neither advised agencies nor private companies on Part D nor consulted for a pharmaceutical company on managed care or reimbursement since 1995, over a decade before Part D existed. (*Id.* at 5.) Janssen then argues that Schafermeyer's previous expert testimony centered on over-inflated drug prices instead of coverage and reimbursement of HIV medications. (*Id.* at 6.) Finally, Janssen argues that Relators attempt to buttress Schafermeyer's credentials by pointing to alleged errors, which is an inappropriate factor to consider when determining the qualification of an expert. (*Id.* at 7–8.)²

As mentioned above, the qualification requirement of Rule 702 is interpreted liberally with a "broad range of knowledge, skills, and training qualify[ing] an expert." *Pineda*, 520 F.3d at 244 (quoting *Paoli*, 35 F.3d at 741). The qualification prong of Rule 702 requires "that the witness possess specialized expertise." *Id.* (quoting *Schneider*, 320 F.3d at 404). "Unlike an ordinary witness, ... an expert is permitted wide latitude to offer opinions, including those that are not based on first[-]hand knowledge or observation." *Daubert*, 509 U.S. at 592.

Schafermeyer earned an M.S. and Ph.D. in Pharmacy Administration, is a licensed pharmacist, has earned credits in business, economics, and marketing, and is currently a Professor of Pharmacy Administration at St. Louis College of Pharmacy. (Schafermeyer Report, Ex. A, at 23.) In a previous role, he "served as the Director of Graduate Studies and headed a Master's degree program in Managed Care Pharmacy." (*Id.* ¶ 1.) Since 1976, Schafermeyer has worked with, taught about, and analyzed the operations of pharmacies, their financial performance, their costs of dispensing, and their reimbursement by private and public prescription programs, including government-supported health care programs such as Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program. (*Id.*) He has also worked with and taught about the operations of managed care organizations and pharmacy benefit managers ("PBMs"). (*Id.*) Furthermore, Schafermeyer has testified in four cases since 2015, but Janssen alleges they were related to over-inflated drug prices and not the issues in this current matter. (*Id.*; Schafermeyer Reply at 6.) According to Janssen, he has not taught such a course since 2005, around when Part D was enacted. (Schafermeyer Moving Br. at 2–4; Reply at 5.)

*10 Schafermeyer has been involved in pharmacy administration for approximately forty-five years. (Schafermeyer Report ¶ 1.) He has taught classes in pharmacy administration, which included reimbursement by private and public prescription programs. (*Id.*) Moreover, he has consulted on matters related to reimbursement. (*Id.*) Even if Janssen's concerns are taken as true, Schafermeyer's long and storied career in pharmacy administration gives him the specialized knowledge required to qualify as an expert under Rule 702. See *Paoli*, 35 F.3d at 741 ("We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications."). Although the time since Schafermeyer taught or worked in the field may be pertinent, the Court finds that these concerns go to the credibility and weight of his testimony, a function better left to trial before a jury. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). With the policy of liberal admissibility in mind, the Court finds that Schafermeyer is qualified to testify about his Coverage and Reimbursement Opinions.

The Court finds that Janssen's argument regarding Schafermeyer's qualifications is unpersuasive and primarily goes to the weight and credibility of Schafermeyer's testimony. As such, the Court will deny Janssen's motion to limit the expert testimony of Kenneth W. Schafermeyer.

D. Janssen's Motion to Exclude Certain Opinions of Aaron E. Glatt

Janssen filed a motion to limit certain testimony of Aaron E. Glatt, ("Glatt Motion," ECF No. 198), along with a brief in support of the Motion, ("Glatt Moving Br.," ECF No. 198-1). Relators opposed the Motion, ("Glatt Opp'n Br.," ECF No. 285), to which Janssen replied ("Glatt Reply," ECF No. 246). Relators identified Glatt as an expert in the approved labels of [Prezista](#) and Intelence, Janssen's marketing of [Prezista](#) and Intelence, and the Speaker Programs. (Chuderewicz Decl., Ex. A, ECF No. 194-3.) Glatt's report provides the following summary of the opinion he intends to offer at trial:

I conclude, with a reasonable degree of medical certainty, that none of these types of promotional messaging were clinically appropriate given the limited FDA approval, available recommendations and guidelines by respected professional and regulatory agencies, and the standard of care for treatment of HIV/AIDS patients in the infectious disease and broader medical community

(Chuderewicz Decl., Ex. A, "Glatt Report" ¶ 9, ECF No. 266.) Glatt's report also contains the following opinion: "There was considerable significance of Janssen's marketing in terms of likely impact on physician's prescribing decisions, potential patient harm, and expansion of the potential market for [Prezista](#) and Intelence." (*Id.* ¶ 11.) Janssen argues that "Glatt opines repeatedly in his report that those practices likely caused physicians to write Intelence and [Prezista](#) prescriptions that they would not otherwise have written" ("Causation Opinion"). (Glatt Moving Br. at 1.) Janssen argues that Glatt's Causation Opinion should be excluded from his report, and he should not be permitted to testify about his Causation Opinion at trial. (*Id.* at 2.) Janssen contends Glatt's Causation Opinion is inadmissible because: (1) "he is not qualified to offer it" and (2) it "is not reliable." (*Id.* at 2, 4.)

In opposition, Relators argue that the challenged testimony is "both within Dr. Glatt's expertise and reliable based on Dr. Glatt's broad experience in the field of drug treatment for HIV-AIDS patients...." (Glatt Opp'n Br. at 7–8.) Relators explain that Glatt's experience is further evidenced by his "years of teaching and consultation with other physicians and students, including specifically about the appropriate selection of drug [therapies for HIV/AIDS patients](#)" and "career on hospital committees," which dealt with the potential impacts of pharmaceutical marketing on physicians and other prescribers. (*Id.* at 8.) Relators explain that Glatt draws on his previous experience but also "carefully describes how the substance or content of Janssen's messaging could mislead physicians and influence their selection and use of Janssen's drugs." (*Id.* at 10–11.) In addition, with respect to Janssen's argument that Glatt's opinion is not reliable, Relators argue that he meets the standard applied to expert witnesses relying on experience because he explains how his experience helped shape his conclusions, why his experience is a sufficient basis, and how his experience is "reliably applied to the facts." (*Id.* at 16.)

*11 In its reply, Janssen argues that "Glatt's Causation Opinion extends beyond the factors that physicians generally consider when making prescribing decisions and impermissibly speculates how all physicians weigh and interpret marketing information when prescribing [Prezista](#) and Intelence to HIV patients." (Glatt Reply at 2.) Janssen emphasizes that Glatt does not have experience in pharmaceutical marketing to support his opinion. (*Id.* at 3.) Further, Janssen focuses on Glatt's methodology, stating "Glatt does not identify any methodology that he used to reach his Causation Opinion." (*Id.* at 5.)

Glatt is a Clinical Professor of Medicine at Icahn School of Medicine at Mount Sinai. (Glatt Report ¶ 1.) Glatt is the Chairman of the Department of Medicine and Chief of Infectious Diseases and Hospital Epidemiologist at South Nassau Communities Hospital. (*Id.*) He is a fellow of the Infectious Disease Society of America, the American College of Physicians, and the Society of Healthcare Epidemiologists of America. (*Id.*) He has practiced in the infectious disease field for over thirty-three years with a "significant focus on treating patients with HIV/AIDS." (*Id.* ¶ 2.) He has authored numerous articles related to HIV/AIDS

drugs and treatment. (*Id.* at 74–81.) Glatt has been the spokesperson for the Infectious Diseases Society of America since 2002 and is a member of several Infectious Disease and HIV committees. (*Id.* at 71–73.)

According to Glatt, Relators retained him to opine on the following issues: (1) the drug treatment for patients with HIV/AIDS during the “Relevant Time Period”³; (2) the clinical issues related to the HIV/AIDS drug regimen that are particularly important to patients and physicians; (3) the FDA-approved labels and marketing indications for *Prezista* and *Intelence*; and (4) the education value of the Speaker programs. (*Id.* ¶¶ 5–7.) In reaching his opinion, Glatt used his professional experience and educational background to assess the FDA label, “the weight of medically accepted standards and the significance of Janssen’s messaging, including the likely impact of physician’s prescribing decisions,” and the “potential patient harm and likely expansion of the market for the drugs.” (*Id.* ¶ 6.)

As mentioned above, an expert’s testimony is admissible when the expert is qualified, the testimony is reliable, and the testimony fits the facts of the case. When an expert relies primarily on experience rather than a scientific study, the expert must “explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.” *Fed. R. Evid.* 702 Advisory Committee Notes to 2000 Amendments. *See also Ford*, 481 F.3d at 219 (reliability may turn on the proposed expert’s “personal knowledge or experience”). However, the party seeking admission for expert testimony must prove (and a court must find) that the expert has sufficient bases to make specific conclusions. *See Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006).

In *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, Pfizer filed a motion to exclude a rheumatologist’s testimony regarding a medicine’s therapeutic properties, the absence of therapeutic advantages over other non-steroidal anti-inflammatory drugs (“NSAID”), and physician prescribing practices, specifically the role of marketing materials in influencing physicians to prescribe the drug. 461 F. Supp. 2d at 275. Plaintiff argued that the rheumatologist’s testimony should have been excluded in its entirety because it was speculative and not based on a reliable methodology. *Id.* at 275–76. The defendant argued that the rheumatologist should have been permitted to testify because his opinions were “based on his 20 years [of] practicing rheumatology and prescribing NSAID therapies for the treatment of chronic pain.” *Id.* at 276.

*12 In *Pfizer*, the court granted narrow exclusions where the rheumatologist did not have a reliable basis for his testimony. *Id.* at 275–78. The court found that the expert’s “20 years practicing rheumatology and prescribing NSAID therapies for the treatment of chronic pain” was “not a sufficiently reliable basis for his broad opinions on the prescribing practices and general understanding of all physicians.” *Id.* at 277. Moreover, the court found that the rheumatologist could “render an opinion on the accuracy of *Celebrex*’s marketing materials” but “not opine as to physicians’ ... understanding of these materials or the effect that these materials had on their prescription choices” because the latter opinions “are speculative and not based on a reliable methodology.” *Id.* Finally, the court found that the rheumatologist did not have a sufficiently reliable basis for his opinions that “prescriptions were heavily influenced by advertising and promotion” because his personal knowledge and experience did not persuade the court that he could “form[] a sufficient basis for his broad conclusions concerning the impact of sales and marketing efforts on ... prescriptions.” *Id.* at 277–78. Ultimately, the court drew a distinction between reliable and unreliable expert testimony from physicians. *Id.* at 275. Because of a physician’s training and expertise, they can opine on prescribing medication, label accuracies, marketing accuracies, comparisons between various medications, and how they would act in a certain situation. *Id.* at 275–77. However, physicians cannot go beyond their expertise to opine about the effect of marketing materials or put forth broad opinions about prescribing practices and the general understanding of all physicians without more expertise. *Id.* at 277.

The Court has considered Glatt’s qualifications and the opinion he intends to offer. The Court finds that Glatt has extensive personal knowledge and expertise in the field of HIV/AIDS drugs and their labels. Glatt is a practicing physician, has practiced medicine for almost forty years, has been involved with infectious disease departments for much of his practice, and has been in several teaching and head positions over the course of his career. (Glatt Report ¶ 1.) He also sat as chair on various hospital committees that dealt “with the potential impact of pharmaceutical advertising on appropriate usage of medications both in the hospital and in the community.” (*Id.* ¶ 5.)

Glatt has personal knowledge of pharmaceutical marketing and advertising throughout his career, including “setting up policies and practices that the hospital should engage in terms of allowing, not allowing pharmaceutical industry representatives to come into the hospital” to prevent undue influence on physicians. (*Id.* ¶¶ 7, 27.) In his current position, Glatt continues to consult with other physicians about recommended drug treatments for patients, and he has seen on numerous occasions the increased usage of a drug for no medical indication after pharmaceutical representatives have visited. (*Id.* ¶¶ 25–30.) Contrary to Janssen's argument, Glatt's personal knowledge and expertise are far greater in comparison to the physician in *Pfizer* on the testimony involved. The Court finds that Glatt's personal knowledge and expertise indicate that he is generally qualified to offer his opinion with respect to HIV, its drugs, its labels, and its marketing.

However, the Court finds inadmissible Glatt's opinions about the effects of Janssen's OL promotions on physicians' prescribing decisions. Although Glatt has some experience with pharmaceutical marketing in hospitals and has firsthand knowledge of many concerns regarding HIV/AIDS due to his career in infectious diseases, he does not have the same qualifications as Sillup, for example, to opine on the effects of OL promotion and marketing. (Glatt Report ¶¶ 1–5; Glatt Report at 91–97.) Relying on the court's guidance in *Pfizer*, this Court will bar Glatt from opining on how Janssen's OL promotion and marketing impacted the physicians' prescribing decisions. 461 F. Supp. 2d at 277–78. Accordingly, the Court grants Janssen's motion to limit the testimony of Aaron E. Glatt.

E. Janssen's Motion to Exclude the Testimony of Virginia B. Evans

Janssen filed a motion to exclude the expert report and testimony of Virginia B. Evans (“Evans Motion,” ECF No. 200), along with a brief in support of the Motion, (“Evans Moving Br.,” ECF No. 200-1). Relators opposed the Motion, (“Evans Opp'n Br.,” ECF No. 281), to which Janssen replied, (“Evans Reply,” ECF No. 244). Relators identified Evans as “an expert in the field of health care compliance.” (Evans Opp'n Br. at 9.) Evans' report provides the following summary of the opinion he intends to offer at trial:

*13 [I]t is my opinion that Janssen's [Prezista](#) and Intelence Speaker Programs did not comply with applicable government and industry standards, and that Janssen did not have an effective compliance program to prevent and detect Speaker Program misconduct. Based on my review and analysis, I conclude that Janssen used its Speaker Programs to pay doctors to induce them to prescribe [Prezista](#) and Intelence, and/ or to reward them for doing so. I further conclude that Janssen paid its Speaker physicians to promote the off-label use of these drugs to other prescribing physicians.

(Chuderewicz Decl., Ex. A, “Evans Report” ¶¶ 5–6, ECF No. 267.) According to her expert report, Relators asked Evans to opine on whether the Speaker Programs were conducted in compliance with the laws, regulations, and guidance in the pharmaceutical industry, and whether Janssen's compliance program was “effective” as that term is understood in the healthcare and pharmaceutical industries. (*Id.* ¶ 5.)

Janssen argues that Evans intends to “offer[] legal advocacy, rather than specialized knowledge, that would not help the trier of fact to understand the evidence or to determine a fact in issue.” (Evans Moving Br. at 2–7.) Aside from the legal conclusions, Janssen also argues that Evans' “opinion that Janssen's compliance program was ‘ineffective’ is inadmissible because she fails to tie her opinions to reliable methods or principles.” (*Id.* at 7–14.)

In opposition, Relators argue that Evans did not provide legal conclusions. (Evans Opp'n Br. at 11.) They contend Evans “analyzed the evidence in the record under applicable government and industry standards, offered her expert opinion in a written expert report, and provided testimony.” (*Id.* at 11–12.) They argue that Evans' report does not improperly summarize evidence

and usurp the role of the jury. (*Id.* at 20–23.) Moreover, Relators contend Evans used reliable methods to form her opinions. (*Id.* at 23–35.)

In its reply, Janssen emphasizes that Evans offers legal advocacy that would usurp the role of the jury and the Court. (Evans Reply at 2.) Also, Janssen reiterates that Evans failed to apply reliable methodology to render her non-legal opinions admissible. (*Id.* at 6.)

The Court has reviewed Evans’ qualifications because her specialized knowledge and experience in health care compliance is relevant to understanding how she formed her opinions and deciding the issue of reliability. Evans graduated from New York University School of Law and is admitted as a member of the bar in several states. (Evans Report ¶ 7; *id.* at 78.) She worked as a federal prosecutor for over twenty-five years but transitioned into private practice in 2005 and started providing health care consulting services. (*Id.* ¶¶ 5–6.) When she first transitioned into private practice, she “managed several Independent Review Organization engagements for health care clients under Corporate Integrity Agreements, conducted compliance risk assessments and internal investigations, and worked with Audit Committees and Internal Audit Departments of large health care providers including hospitals, insurers, a national retail pharmacy chain, and an international pharmaceutical company.” (*Id.* ¶ 6.) In 2010, she became partner at a large firm’s Health Law practice where she represented health care providers in civil and criminal investigations. (*Id.* ¶¶ 6–7.) During that time, she also became a compliance resource for pharmaceutical companies, drug manufacturers, and physician practices. (*Id.* ¶ 6.) She wrote and reviewed compliance policies for many clients and negotiated settlements with state and federal health care agencies in cases involving the FCA, FDA, and other health care matters. (*Id.*) At one point, Evans served as a Vice President, Compliance Officer, and General Counsel for a hospital system. (*Id.* ¶ 7.) Evans also has experience working as a Senior Legal Editor for ThomsonReuters’ Health Care & Life Science legal journal, and she is certified in Health Care Research Compliance. (*Id.*)

*14 In her report, Evans used specialized knowledge as a health care compliance expert to determine whether Janssen maintained an effective compliance program by reviewing its compliance policies. Evans noted that she reviewed numerous documents before reaching her conclusions, including but not limited to Janssens’ compliance policies on the Speaker Programs, documents concerning its Speaker Programs (*e.g.*, procedures, promotional policies, management guide, and internal emails and communications), summary reports of investigations, honoraria reports, return on investment reports, data collection efforts, transcripts of depositions of witnesses, and Janssen’s responses to discovery request. (*Id.* ¶ 8; *id.* at 81–84.) More specifically, Evans reviewed Janssen’s Speaker Programs to determine if they complied with the standards set forth in the Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Guidance”) written by the Office of Inspector General (“OIG”) of the Department of Health and Human Services. (*Id.* ¶¶ 8–9.) She sought to determine whether Janssen implemented “controls,” as recommended by OIG guidance, to prevent its Speaker Programs from being used to improperly influence physicians’ prescribing behavior. (*Id.* ¶ 9.) Evans also reviewed Janssen’s compliance program and other internal documents to determine whether Janssen complied with its own policies. (*Id.*) In addition to the OIG Guidance, Evans also relied on other materials about industry standards and practices that help manufacturers implement and maintain effective compliance programs. (*Id.* ¶¶ 9–10.)

After reviewing Evans’ approach, the Court rejects Janssen’s argument that Evans’ methodology was “unreliable and litigation-driven.” (Evans Moving Br. at 9.) To the extent Janssen takes issue with the evidence Evans relies upon to render her non-legal opinions, Janssen may cross-examine her and present evidence to the contrary at trial. *Krys v. Aaron*, 112 F. Supp 3d 181, 192 (D.N.J. 2015) (quoting *Daubert*, 509 U.S. at 595). See also *MicroStrategy Inc. v. Business Objects, S.A.*, 429 F.3d 1344, 1355–356 (Fed. Cir. 2005) (explaining that an expert “must consider *enough* factors to make his or her opinion sufficiently reliable in the eyes of the court ... [but the] expert need not consider *every* possible factor to render a ‘reliable’ opinion”). The Court is not required to preclude Evans’ expert testimony simply because Janssen believes she “could have performed ... her analysis in a better manner.” *Pfizer*, 461 F. Supp 2d at 274. For the reasons stated above, the Court finds that Evans used “reliable principles and methods” to reach her conclusion concerning the effectiveness of Janssen’s compliance program, and her opinion is supported by “sufficient facts and data.” See *Fed R. Evid.* 702(b), (c).

Moreover, Evans' testimony about the industry compliance standards and her opinion that Janssen did not have an effective compliance program is admissible because it would help "the trier of fact to understand the evidence [and] to determine a fact in issue...." *Fed. R. Evid.* 702(a). Evans' opinion would help the jury determine whether Janssen's "conduct or actions meet the underlying bases for an ultimate issue" to be decided in this case. *Krys*, 112 F. Supp. 3d at 193. However, Evans' opinion that "Janssen used its Speaker Programs to pay doctors to induce them to prescribe *Prezista* and *Intelence*" is inadmissible because it is a legal conclusion. *Berkeley*, 455 F.3d at 217. Whether Janssen used its Speaker Programs to induce doctors to prescribe *Prezista* and *Intelence* is an issue for the jury because it decides an element of the AKS claims. *See* 42 U.S.C. § 1320a-7b(b) (2)(B). Although *Federal Rule of Evidence* 704(a) allows an expert to proffer testimony that "embraces an ultimate issue to be decided by the trier of fact," the ultimate issue rule does not enable an expert to tell the jury what result to reach. *Krys*, 112 F. Supp. 3d at 192. The Court agrees with Janssen that this is a question of intent for the jury, and Evans cannot provide testimony concerning state of mind or culpability. *Id.* at 203.

The Court, therefore, will grant in part and deny in part Janssen's motion to exclude the expert testimony of Virginia Evans.

F. Janssen's Motion to Exclude the Testimony of Israel Shaked and Ian Dew

Janssen filed a motion to exclude the testimonies of Israel Shaked and Ian Dew, ("Shaked Motion," ECF No. 202), along with a brief in support of the Motion, ("Shaked Moving Br.," ECF No. 202-1). Relators opposed the Motion, ("Shaked Opp'n Br.," ECF No. 280), to which Janssen replied, ("Shaked Reply," ECF No. 248). Relators retained "Shaked to perform statistical analyses of the prescription claims data and to opine on issues of causation and damages." (Shaked Opp'n Br. at 1.) Shaked's expert report provides many opinions he intends to offer at trial, including: the positive relationship between compensation paid to physicians and subsequent prescriptions written for *Prezista* and *Intelence*; the opinion that Janssen's conduct "influenced" OL prescriptions that were then reimbursed by the government for the relevant periods; and the total damages related to Janssen's alleged violation of the FCA and AKS. (Chuderewicz Decl., Ex. A, "Shaked Report" ¶¶ 13–145, ECF No. 268.) Shaked performed twelve different analyses in which he calculated various metrics to explain the relationships between payments to speakers, effects of payments on prescribing physicians, and the relationship between speakers and non-speakers. (*Id.* at 35–63.) In reaching his conclusions, Shaked relied on Ian Dew for analytical support.⁴ (*Id.* ¶ 14; Chuderewicz Decl., Ex. D, "Dew Rebuttal Report" at 3, ECF No. 268-2.)

*15 Janssen challenges the reliability of Shaked's opinions and, by proxy, of Dew's opinions. (Shaked Moving Br. at 4.) Janssen also seems to challenge Shaked's qualification by claiming that he does not have the requisite experience to opine on medical claims because his work centers on financial analyses.⁵ (*Id.* at 4.) First, Janssen argues that "Shaked's general causation opinions relating to [OL] promotion and speaker payments should be excluded because they are based on an unreliable methodology for assessing causation." (*Id.* at 10–20.) It contends that Shaked's "[c]orrelation analyses are not generally accepted methods for assessing causation" and fails to consider "confounding factors that may affect physicians' prescribing decisions." (*Id.* at 11, 15.) Second, Janssen argues that "Shaked's general causation opinions relating to [OL] promotion also should be excluded because the two variables being measured in his correlation analyses are based on unsupported assumptions that do not fit the facts of this case and result in an unreliable methodology." (*Id.* at 20–27.) Janssen contends that Shaked's definition of an "influenced" prescriber and his attribution of a patient's lifelong prescriptions to the first prescriber are both variables based on unsupported assumptions. (*Id.* at 20, 24.) Third, Janssen argues that "Shaked's specific causation opinions identifying false claims and estimating damages resulting from Janssen's alleged improper promotion should be excluded because they are based on unsupported assumptions and errors that do not fit the facts of this case and result in an unreliable methodology." (*Id.* at 27–30.)

In opposition, Relators argue that "Shaked has excellent support for his analyses and opinions here, and his opinions easily satisfy the applicable standards of reliability and admissibility." (Shaked Opp'n Br. at 3.) They argue that Shaked accounted for confounding variables, has a basis for assumptions and definitions for his damages and causation analyses, and can prove causation under the FCA through a general causation analysis rather than a "but for" analysis. (*Id.* at 3–6.) In addition, Relators explain that Shaked is an expert in statistics and uses "common and well-established methods to perform his analyses," applying

the methods to comparable groups. (*Id.* at 2.) They note that Shaked has the educational, academic, and industry background necessary to qualify as an expert. (*Id.*)

In its reply, Janssen reiterates that Shaked's general causation opinions are inadmissible because they fail to satisfy the reliability requirement of [Federal Rule of Evidence 702](#). (Shaked Reply at 2.) Janssen argues that Shaked cannot prove any existence of a causal relationship because his assumption that all of Janssen's contacts “influenced” physicians has no reliable basis in the facts. (*Id.* at 4; *see id.* at 11, n.8.) Emphasizing its point that two-variable correlation analyses are not a generally accepted method for assessing causation, Janssen argues that the lack of a randomized control experiment and the lack of multiple regression analyses cause his general causation opinion to be unreliable. (*Id.* at 5–11.)

The parties' disagreement centers on whether Shaked's analyses have “good grounds” for his conclusions. The “good grounds” analysis implicates the reliability prong; once determined, the fit of the testimony to the facts of the should be adjudged. *See Daubert*, 509 U.S. at 598. “The evidentiary requirement of reliability is lower than the merits standard of correctness.” *Paoli*, 35 F.3d at 744. “An expert is ... permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury.” *Walker v. Gordon*, 46 Fed. App'x 691, 695–96 (3d Cir. 2002). An expert's report and testimony are reliable if the expert has “good grounds” for his or her opinions. *Paoli*, 35 F.3d at 744. When evaluating whether a particular scientific methodology is reliable, the Third Circuit has instructed district courts to consider the following non-exhaustive factors: (a) whether a method consists of a testable hypothesis; (b) whether the method has been subject to peer review and publication; (c) the known or potential rate of error; (d) the existence and maintenance of standards controlling the technique's operation; (e) whether the method is generally accepted; (f) the relationship of the technique to methods which have been established to be reliable; (g) the qualifications of the expert witness testifying based on the methodology; and (h) the non-judicial uses to which the method has been put. *Id.* at 742, n.8 (citation omitted). *See also Pineda*, 520 F.3d at 247–48.

*16 The Court reviewed Shaked's report to determine whether he used methods with good grounds to reach his general causation opinions. The Difference of Two Population Means Test (the two-factor correlation analysis Janssen references) determines whether there is a statistically significant difference between two independent population means. (Shaked Report at 73.) If the z-score is higher than the critical value, then there is a statistically significant difference between the two populations. (*Id.* at 73.) Here, Shaked clearly explains his rationale for setting up tests, tests each of his hypotheses (e.g., whether payments “influenced” physicians) against the negative hypotheses (e.g., whether payments did not “influence” physicians), and used z-scores to determine whether the results were statistically significant. (Shaked Report ¶¶ 76, 96, 105, 131, 140.) Moreover, Shaked calculated the Spearman Rank Correlation values for dollar amounts paid to speakers and their dollar amount of prescriptions. (*Id.* at 36.) As understood by the Court and expressed by Shaked, the Spearman Correlation Test measures the positive relationship between two variables; a value of “-1” implies a weak association, a value of “0” implies no association, and a value of “1” implies a positive association. (Shaked Report at 73–74.) The Spearman Rank Correlation Significance Test analyzes the strength of the correlation test and the possibility that the correlation is by chance. (*Id.* at 74.) Furthermore, contrary to Janssen's argument that Shaked did not run regressions, Shaked ran multiple regressions on the data when challenged by Anupam Jena; however, Shaked chose not to include it in the supplemental report because he believed that the identical results did not need to be included in his report. (Chuderewicz Decl., Ex B., “Shaked Dep.” 291:10–25, ECF No. 202-4.) With positive values, high z-scores, and high t-values, the values are statistically significant (*i.e.*, cannot be rejected) under accepted statistical checks.⁶ (Shaked Report at 74.) As such, the Court finds that Shaked's report has “good grounds” and is, therefore, reliable. Since Shaked uses data pertinent to the facts of the case, the Court finds that his analysis is also relevant to the case at hand.

The *Reference Manual on Scientific Evidence* does note that randomized controlled experiments generally are a better measure of causation than observational studies. Federal Judicial Center, 220 (3d ed. 2011). Although the Court does not doubt that Shaked has the capacity to make such a decision, it would be prudent to probe the reason for his choice. Shaked collected the data for his analyses from a variety of sources, including state databases, and explains that his analysis is a controlled experiment due to the nature of the data. (Reply at 9; Shaked Dep. 290:7-9.) Each of Shaked's checks for significance imply that the values are not insignificant. (Shaked Report ¶¶ 76, 89, 96, 105, 119, 131, 140.) Furthermore, Shaked ran multiple checks on his analyses to determine whether the conclusions were sound. (Shaked Dep. 291:18-25.) Holding that the lack of complete control over all

aspects of a study is sufficient to defeat the reliability of the study would mitigate the use of studies in many cases heard in this Court. *See, e.g., In re Johnson & Johnson Talcum Powder Products Mktg.*, 509 F. Supp. 3d 116, 166–67 (3d Cir. 2020) (“The Court cannot deem Plaintiffs’ experts’ opinions unreliable simply because they determined that the case-control studies were entitled to greater weight than the cohort studies, particularly since the experts’ explanations of their methods were supported by scientific reasons.”).

Considering that Shaked has proven that the variables are strongly correlated through a reliable methodology, the question becomes whether Shaked has a strong basis for asserting that the kickbacks resulted in physicians writing more prescriptions for *Prezista* and *Intelence*. That is a question of weight, not of reliability. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 167 (“Defendants may disagree with the experts’ interpretations of those studies and their usefulness, but such issues go to the weight of the experts’ testimony, and not their reliability.”). Many of Janssen’s arguments attack Shaked’s assumptions and question his choice of methodology: the proper venue for such arguments is at trial during cross-examinations. *See Daubert*, 509 U.S. at 596. The Court’s role at this point is to determine whether the methodology is reliable. *Id.* As it has, the Motion to exclude Shaked’s and Dew’s report and testimony is denied.

G. Relators’ Motion to Exclude the Testimony of Jon Smollen

*17 Relators filed a motion to exclude the expert report and testimony of Jon Smollen (“Smollen Motion,” ECF No. 179), along with a brief in support of the Motion, (“Smollen Moving Br.,” ECF No. 276). Janssen opposed the Smollen Motion, (“Smollen Opp’n Br.,” ECF No. 210), to which Relators replied, (“Smollen Reply,” ECF No. 254). Janssen identified Smollen as a rebuttal expert to Relators’ compliance expert, Virginia Evans, and as an individual who has “specialized knowledge” and analysis regarding “Janssen’s efforts to comply with the AKS.” (Smollen Opp’n Br. at 1.) Smollen’s report provides the following summary of the opinion he intends to offer at trial:

Based on my professional experience and expertise, it is my opinion that throughout the Review Period, Janssen proactively identified compliance risks arising from its Speaker Programs, designed and implemented compliance policies and controls to mitigate those risks, and effectively operationalized its policies.

(Ellerbe Decl., Ex. 1, “Smollen Report” at 4, ECF No. 279.) Smollen opined on (1) whether Janssen had effective compliance policies in place to minimize the risk that its Speaker Program violated the AKS (“Effective Compliance Opinion”), and (2) whether Janssen had effective compliance policies in place overall (“Overall Compliance Opinion”). (Smollen Motion at 4.) After considering OIG and PhRMA (“Pharmaceutical Research and Manufacturers of America”) Code guidance, the testimony and evidence provided by Janssen, and his own professional judgment, Smollen concluded the following: (1) Janssen had effective compliance policies to prevent violation of the AKS; and (2) Janssen had effective compliance policies in place overall. (*Id.* at 4.)

Relators argue that Smollen’s Effective Compliance Opinion is unreliable because his opinions regarding Janssen’s effective compliance “is based on a skewed and unreliable consideration of very limited select evidence in the case and simply ignores a wealth of evidence that contradicts his opinions.” (Smollen Moving Br. at 7.) Relators also argue that Smollen’s Overall Compliance Opinion is irrelevant, unreliable, and likely to confuse the jury because “it is not relevant to any issues in this case[,] fails to even consider the issue of [OL] marketing at all[,] ... fails to consider the overwhelming evidence regarding Janssen’s [OL] marketing scheme[,] and is likely to confuse the jury.” (*Id.*) Relators point to examples of “Smollen providing superficial opinions without ever delving into the underlying facts in the record.” (*Id.* at 24.)

In opposition, Janssen argues that Smollen’s testimony “would help the jury ‘understand the evidence’ and ‘determine a fact in issue’ (that is, whether Janssen intended to violate the AKS).” (Smollen Opp’n Br. at 1.) Janssen argues that Smollen’s reluctance

to adopt Relators' view of the case for his Effective Compliance Opinion is not a basis for reliability. (*Id.* at 3.) He "reviewed Relators' witnesses' testimony, the testimony from other witnesses, and hundreds of documents, including Relators' witnesses' emails, compliance monitoring and investigation logs, compliance trainings, compliance communications, compliance risk assessments, and compliance policies." (*Id.* at 4–5.) Janssen states that "Smollen did not ignore key deposition testimony" and gave "thoughtful consideration" to all the evidence. (*Id.* at 7, 9.) With respect to Smollen's Overall Compliance Opinion, Janssen argues that Smollen's opinion is relevant and that he opined on the same relevant topics as Evans. (*Id.* at 10.) According to Janssen, Smollen "considered how Janssen operationalized compliance across the company and across all risk," which was also considered in Evans' expert report. (*Id.* at 12.)

***18** In its reply, Relators reiterated that Smollen "ignored substantial deposition testimony" from Mark Wilhelm and Sara Strand⁷ and, when asked about this testimony, Smollen "admitted that Janssen's practices violated its own written policies, applicable industry standards, and the law." (Smollen Reply at 1–2.) Relators also allege that Smollen made credibility determinations among witnesses, which was inappropriate for experts to do. (*Id.* at 5–8.)

The Court first considers Smollen's qualifications before addressing the reliability of his opinions. Smollen is qualified to opine on compliance issues due to his education and experience. He held leadership and advisory positions in several pharmaceutical companies, assisted in establishing and enhancing U.S. and global compliance programs, and currently teaches compliance and ethics at Temple Law School. (Smollen Report at 10–12.) In reaching his opinions, he thoroughly walks through Janssen's regulatory procedure, applies the PhRMA Code and OIG recommendations, compares Janssen's policies to the industry standard, and applies the same framework—like Relators' expert, Evans—to come to a different conclusion. (*Id.* at 67.) In this instance, Smollen's report is relevant because it discusses a pertinent issue of the case (compliance), rebuts Relators' experts, and provides helpful information to the jury. As the Court previously mentioned, "the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties." *Berkeley*, 455 F.3d at 217. Here, the Court finds that the Overall Compliance Opinion and Effective Compliance Opinion are reliable because Smollen applied his professional judgment and expertise in a reliable manner.

Relators argue that Smollen should have taken note of Wilhelm's and Strand's testimony in his expert opinion. As a reminder, "[a]n expert is ... permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury." *Walker*, 46 Fed. App'x at 695–96. See *In re Johnson & Johnson*, 509 F. Supp. 3d at 167 ("Defendants may disagree with the experts' interpretations of those studies and their usefulness, but such issues go to the weight of the experts' testimony, and not their reliability."). Although he did not mention Wilhelm, Smollen took note of Strand's testimony.⁸ (Smollen Report at 56.) Smollen's failure or unwillingness to respond to testimony from certain witnesses is an issue for cross-examination. Moreover, to the extent Relators assert that Smollen agreed Janssen violated its policies, a quick look at Smollen's deposition reveals that Smollen *only* agreed that certain facts, if proven true, could hypothetically constitute violations of written policies and statutes. (Ellerbe Decl., Ex. 2, "Smollen Dep." 77:10-80:21, 82:15-89:21, 93:3-95:23, 97:8-101:23, ECF No. 279-1.)

***19** Relators raise other arguments that attack assumptions and do not go to the reliability of Smollen's report; as mentioned above, the proper venue for such arguments is trial, not a *Daubert* motion. *Daubert*, 509 U.S. at 596. Accordingly, Relators' motion to exclude Smollen's report and testimony is denied.

H. Relators' Motion to Exclude Certain Opinions of Anupam Jena

Relators filed a motion to limit the opinions of Anupam Jena, ("Jena Motion," ECF No. 181), along with a brief in support of the Motion, ("Jena Moving Br.," ECF No. 277). Janssen opposed the Motion, ("Jena Opp'n Br.," ECF No. 215), to which Relators replied ("Jena Reply," ECF No. 253). Janssen identified Jena to opine on issues of causation and damages, and to respond to Shaked's opinions and analyses on those same topics. (Chuderewicz Decl., Ex. A, ECF No. 194-3.)

Jena organized his report into three main sections: (1) HIV treatment background; (2) assessing causation with respect to Janssen's alleged improper promotion in the current case; and (3) assessing causation with respect to Janssen's speaker payments in the current case. (Ellerbe Decl., Ex. 25, "Jena Report" ¶¶ 16–63, ECF Nos. 279-6.) Jena organized his rebuttal report in two main sections: (1) a discussion of Shaked and Dew's causation conclusions ("Causation Opinion"), and (2) a discussion of Shaked's damages estimates ("Damages Opinion"). (Ellerbe Decl., Ex. 24 "Jena Rebuttal Report" ¶ 3, ECF No. 279-5.) In sum, Jena's reports conclude: (1) Shaked's analysis with respect to causation is flawed because he did not use the appropriate data, methods, and accounting for external factors to correctly conclude that Janssen caused false claims to be written through speaker payments and OL marketing; and (2) the correct damages calculation for Relators' claims is approximately \$0 once the analyses accounts for the purported issues. (Jena Report ¶¶ 10–15, Jena Rebuttal Report ¶¶ 12, 14, 63, 122–125.)

Relators seek to strike portions of Jena's reports and testimony that "are based on erroneous legal principles or which implicate such principles."⁹ (Jena Moving Br. at 4.) Relators contend that certain parts of Jena's report are inadmissible because: (1) he "applies a standard that is contrary to the law"; (2) he "ignored substantial evidence in the record"; and (3) his opinions on damages "have no basis in the law and do not support reducing damages to zero." (*Id.* at 8, 17, 19.) Relators argue that Jena's requirement of a "direct causal link" is "directly contrary" to the law regarding liability and causation under the FCA. (*Id.* at 12.) Thus, Relators argue that Jena's opinions are unreliable, irrelevant, and confusing to a jury. (*Id.* at 14.) Relators also argue that Jena failed to review evidence and reviewed only five of the eighteen depositions taken in this case. (*Id.* at 17.) Relators contend that these purported issues cause Jena's Damages Opinion to be unsupported and thus inadmissible. (*Id.* at 20.)

***20** In opposition, Janssen argues that "Jena appropriately evaluated the issues of causation and claimed damages from a scientific perspective using his broad experience in the fields of economics, statistics, and medicine." (Jena Opp'n Br. at 1.) According to Janssen, Jena opines on whether Shaked's correlation analyses are sufficient to show a causal relationship between promotion and prescription numbers or payment and prescription numbers, not whether there is a direct causal relationship between each respectively. (*Id.* at 3–4.) As such, Janssen argues that Jena's opinion is consistent with the generally accepted standards in economics and medicine, as well as the relevant legal standards under the FCA and admission of scientific evidence. (*Id.* at 9.) Janssen further argues that Jena's opinions are based on a sufficient factual foundation, consisting of what he considered to be pertinent court documents and publicly available materials. Finally, Janssen argues Jena's removal of and reductions to Shaked's damages estimates are appropriate under FCA law. (*Id.* at 22–27.)

In its reply, Relators emphasize that Jena applies a direct "but for" test rather than the "substantial factor" test. (Jena Reply at 1–2; Ellerbe Decl., Ex. 23, "Jena Dep." 59:4-60:4, ECF No. 279-5.) Relators argue that Jena's opinions are premised on the application of a "but for" causation; to this point, Relators argue that Jena admitted to using "but for" causation analysis in his deposition. (Jena Reply at 2–3; *see* Jena Dep. 59:4-60:4.) Furthermore, Relators take issue with Jena's position that "prescriptions written 6 months after Janssen's unlawful conduct should not be included in the case for purposes of causation or damages[.]" arguing that the FCA and AKS do not impose strict temporal cutoffs for false claims. (Jena Reply at 9–10.) Relators also argue that Jena should have considered Wilhelm's and Strand's testimony when considering causation and damages. (*Id.* At 11–13.) Finally, Relators argue that certain of Jena's Damages Opinion is contrary to applicable law because legal precedents do not support his damages calculations. (*Id.* at 13–15.)

Jena is appropriately qualified to opine on the matters in his report. Though Jena does not hold any degrees in statistics, he holds a Ph.D. in Economics and has extensive experience studying and analyzing physician behavior in the microeconomic context. (Jena Report at 35, 41–42, 44–60.) Jena uses the same data as Shaked, "corrects" Shaked's data, methodology, and conclusions (an appropriate subject for a rebuttal expert and an important point of view for the jury), and puts forth calculations based on Jena's expertise *and* Janssen's defense. (*Id.* at ¶¶ 60–63; Jena Rebuttal Report ¶¶ 22–45, 66–125.) Thus, Jena reliably applies his expertise to his Causation Opinion and Damages Opinions, raising criticisms and concerns about Shaked's methodologies. (*Id.*) Although Relators may critique Jena's assumptions, the Court finds that Jena's Causation Opinion and Damages Opinions are reliable because they stem from Jena's analytical modeling expertise and arise from the same set of data Shaked utilized. Furthermore, the Court finds that Jena's opinions are relevant because they provide Janssen's views of causation and damages based on Janssen's view of the facts.

Relators' motion and reply focus heavily on Jena's supposed improper application of a legal standard to the facts of the case. (Jena Reply at 5–6.) Relators argue that the application of an improper legal standard causes Jena's opinion to not fit the facts of the case. (*Id.* at 1–3.) If this were true, it would be a cause for concern. The Court does not find support for Relators' argument that Jena is applying the incorrect legal standard to reach his conclusion. In his report, Jena points to other factors that doctors may consider, which are supported by his own study of doctors' behavior and his own practice of medicine. (Jena Report at 35, 41–42, 44–60.) He discusses his rationale for excluding certain calculations and how his method differs from Shaked's. (*See, e.g.*, Jena Rebuttal Report at ¶¶ 114–24.)

*21 Where Relators point to Jena's testimony as bases for exclusion, the testimony does not support what Relators argue. As one of their primary bases for exclusion, Relators argue that Jena agreed that he applied direct (“but for”) causation principles during his deposition. (Jena Dep. 59:19-60:4.) Jena admitted several times that he is testifying as a doctor and economist, not as a lawyer. (Jena Dep. 61:6-12.) As such, his testimony's reliability and relevance should be considered with respect to his expertise in these fields. The Court does not find it surprising that Janssen's expert, opining in support of Janssen's defense with respect to causation, discusses at length the absence of direct evidence in the record as to causation. However, to the extent that Relators believe that Jena applies the incorrect legal test with respect to causation, that issue can be adequately tested by cross-examination. Ultimately, the Court will articulate the proper legal standard for causation to the jury.

Relators criticize Jena's damage reductions as contrary to law. (Jena Reply 13–15.) In part, Relators point to *ZF Meritor* as proof that Jena's report and testimony should be excluded because it apparently shows that an expert cannot form a reliable opinion through a selective review of the evidence. (Jena Moving Br. at 17–18.) *ZF Meritor* supports the notion that existence of conflicting evidence is not a basis on which to exclude an expert's testimony. 696 F.3d 254, 290 (3d Cir. 2012). “The respective credibility of Plaintiffs’ and [Defendant]’s experts [is] a question for the jury to decide.” *Id.* at 290. The damages expert in *ZF Meritor* was excluded because he could not reliably estimate damages from speculative assumptions and the facts on the record. *Id.* at 294. Here, the facts are bare insofar, as noted in this Court's recent decision denying Summary Judgment, most of the material facts in this case are in dispute. Additionally, the assumptions arise from each party's view of the case; because no facts have been proven at this point, it is difficult for the Court to determine whether Jena's (or Shaked's) assumptions are indeed speculative.

“[E]xclusion of critical evidence is an ‘extreme’ sanction....” *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710 (3d Cir. 1997). Although Relators may disagree, Jena's opinions are informed by Janssen's version of events, which is not a basis to exclude an otherwise reliable and relevant opinion. Accordingly, the Court will deny Janssen's motion to exclude the expert testimony of Anupam B. Jena.

I. Relators’ Motion to Limit the Testimony of Eric S. Rosenberg

Relators filed a motion to limit the testimony of Eric S. Rosenberg, (“Rosenberg Motion,” ECF No. 183), along with a brief in support of the Motion, (“Rosenberg Moving Br.,” ECF No. 278). Janssen opposed the Motion, (“Rosenberg Opp'n Br.,” ECF No. 209), to which Relators replied (“Rosenberg Reply,” ECF No. 255). Janssen identified Rosenberg as an expert in infectious diseases, [HIV therapies](#), and strategies surrounding the management of HIV-infected individuals. (Ellerbe Decl., ECF No. 187-3 at 3–4; Rosenberg Reply at 1.)

Rosenberg is Janssen's HIV expert and the opposing expert to Relators' HIV expert, Dr. Aaron Glatt. (Ellerbe Decl., Ex 28, “Rosenberg Rebuttal Report” ¶ 3, ECF No. 279-8.) Rosenberg's report provides an overview of a general practitioner's choices when treating a patient with HIV/AIDS, goals of treatment, materials doctors may use to reach their goals of treating patients with HIV/AIDS, and Rosenberg's experience treating patients with HIV/AIDS. (Ellerbe Decl., Ex. 29, “Rosenberg Report” ¶¶ 9–13, ECF No. 279-9.) Rosenberg's rebuttal report provides additional context on the treatment of HIV/AIDS patients with OL uses of medications, comments on Glatt's report, and provides Rosenberg's personal experience with treating such patients. (Rosenberg Report ¶¶ 34, 42–46; Rosenberg Rebuttal Report ¶¶ 3, 7, 13, 14–16, 19.)

Relators have asked the Court to preclude Rosenberg from testifying beyond clinical or medical background about HIV/AIDS and the types of drugs used in its treatment. (Rosenberg Moving Br. at 5.) Relators assert Rosenberg's report and testimony is inadmissible because: (1) Rosenberg's personal approach to prescribing drugs and utilizing multiple sources of information is irrelevant, and unreliable with no fit to the issues of the case; and (2) testimony about appropriate OL use of drugs is irrelevant to drug marketing practices at issue in the case and is likely to mislead the jury. (*Id.* at 13–14.) Relators do not challenge the use of Rosenberg's testimony for “providing medical background and explanations about HIV/AIDS and the drugs used to treat it,” but they do request that this Court limit Rosenberg's testimony when he goes beyond this function. (Rosenberg Reply at 4.)

***22** In opposition, Janssen argues that Rosenberg's testimony is reliable due to his experience and his testimony is relevant because it is a key component of Janssen's causation defense. (Rosenberg Opp'n Br. at 1.) Janssen contends Rosenberg's testimony is reliable because it comes from his experience as a physician specializing in HIV/AIDS. (*Id.* at 4.) Furthermore, Janssen claims that Rosenberg does not opine on inadmissible topics, such as testimony “concerning what all doctors generally consider.” (*Id.* at 5.) Finally, Janssen claims that Rosenberg's testimony is relevant because it would help the jury understand Janssen's causation defense. (*Id.* at 7–8.)

Relators argue there are three “fatal problems” with Janssen's argument. (Rosenberg Reply at 6.) First, Janssen attempts to use Rosenberg to opine as to the effects of OL marketing even though Rosenberg himself readily admits he does “not feel qualified to offer an expert opinion regarding the effects of promotional marketing.” (*Id.* at 5.) Second, Janssen improperly attempts to misconstrue Rosenberg's testimony as applicable to other doctors. (*Id.* at 7.) Relators contend Rosenberg did not offer his opinion to speculate on how other HIV experts treat HIV patients; instead, Rosenberg's report explains what sources of information he relies on when deciding which medication to prescribe. (*Id.*) Third, the court should reject the general concept that doctors glean knowledge from various sources because it is well within an average layperson's understanding. (*Id.* at 7–8.) For these points, Relators ask the Court to exclude all aspects of Rosenberg's opinions beyond the clinical or medical background he provides about HIV/AIDS and the types of drugs used to treat it.¹⁰ (*Id.* at 15.)

The Court has reviewed Rosenberg's qualifications. He has a plethora of experience diagnosing and treating patients with HIV/AIDS and has many journal articles on treating HIV/AIDS. (Rosenberg Report at 24–26, 30–40.) The Court finds that Rosenberg is qualified to opine on treating and prescribing HIV/AIDS patients. As such, the Court finds that Rosenberg's professional opinions on HIV/AIDS are very reliable. Rosenberg's personal opinions about prescribing drugs, using multiple sources of information, and the appropriate OL use of drugs are relevant to Janssen's causation defense. Accordingly, the Court finds that Rosenberg's opinions also fit the facts of the case.

The Court agrees with Relators that any attempt to move beyond the purviews of explaining how Rosenberg reaches his prescription decision would be inadmissible. However, Rosenberg has not. He clearly delineates what his testimony and report opine on (his methods for prescribing HIV/AIDS medications to patients) and what it does not (marketing, what the average doctor should do). (Rosenberg Report ¶¶ 34, 42–46; Rosenberg Rebuttal Report ¶¶ 3, 7, 13, 14–16, 19.) As the Court found above, Rosenberg is qualified to opine on the subject through his credentials and experience, has good grounds to discuss such topics due to his extensive experience as an HIV/AIDS specialist, and it fits a point that Janssen is raising as a defense (that a doctor considers a variety of factors in prescribing medicine). The Court finds that these concerns can be raised at trial if they are salient. See *Daubert*, 509 U.S. at 596. Therefore, the Court will deny Relators' Motion to limit certain opinions of Eric S. Rosenberg.

IV. CONCLUSION

***23** For the foregoing, the Court rules as follows:

1. Janssen's Motion to Exclude the Testimony of O'Reilly is GRANTED in part and DENIED in part. Specifically, O'Reilly's testimony is limited to background information regarding the drug approval process, misbranding in general, the mechanism by which the government reimburses for prescriptions, and his observations regarding Janssen's compliance efforts. As discussed, O'Reilly is not permitted to provide legal conclusions.

2. Janssen's Motion to Exclude the Testimony of Sillup is DENIED.
3. Janssen's Motion to Exclude Certain Opinions of Schafermeyer is DENIED.
4. Janssen's Motion to Exclude Certain Opinions of Glatt is GRANTED. Glatt will not be permitted to opine on how Janssen's OL promotion and marketing impacted physicians' prescribing decisions.
5. Janssen's Motion to Exclude the Testimony of Evans is GRANTED in part and DENIED in part. Evans will not be permitted to testify that Janssen used its Speaker Programs to induce doctors to prescribe Prezista and Intelence.
6. Janssen's Motion to Exclude the Testimony of Shaked and Dew is DENIED.
7. Relators' Motion to Exclude the Testimony of Smollen is DENIED.
8. Relators' Motion to Exclude Certain Opinions of Jena is DENIED.
9. Relators' Motion to Exclude Certain Opinions of Rosenberg is DENIED.

An appropriate order follows.

All Citations

Slip Copy, 2022 WL 94535

Footnotes

- 1 Between 2006 and 2013, Relator Jessica Penelow worked as a sales consultant for Tibotec Therapeutics, a subsidiary of Johnson & Johnson that became known as Janssen in 2011. ("Second Am. Compl." ¶ 47, ECF No. 90.) While working for Tibotec, she marketed several HIV drugs, including Prezista and Intelence, to doctors in Manhattan. (*Id.*) Similarly, in 2006, Relator Christine Brancaccio started working for Janssen as a sales representative and marketed Prezista and Intelence to providers in Long Island and Queens. (*Id.* ¶ 49.)
- 2 In its reply, Janssen appears to raise the issue of reliability for the first time. (Reply at 3–6.) "An issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue ... will not suffice to bring that issue before this court.'" *Laborers' Int'l Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994). In addition, although both parties argue these points, the Court does not have a sufficient basis to rule whether Schafermeyer's testimony is reliable because the argument was, at best, unclear in the moving brief. This finding is supported by the fact that neither party has effectively argued for or against the factors for the reliability of Schafermeyer's testimony. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 854 (3d Cir. 1990) ("The adversarial process upon which our legal system is based assumes that a fact finder will give the parties an adequate opportunity to be heard; if it does not, it cannot find facts reliably.").
- 3 As used by the parties and their experts, "Relevant Time Period" (as well as "Review Period" or "relevant periods") refers to the period of 2006 to 2014, when Janssen's alleged misconduct occurred. (Glatt Report ¶ 2.)
- 4 Ian Dew is a partner at Steck Consulting and has over twenty years of experience in data analysis. (*Id.* ¶ 17, n.6) Shaked utilized Dew to query databases of ADAP, Medicaid, and Medicare. (*Id.*) Shaked describes the data he requested from Dew throughout his report. (*Id.*)

- 5 Janssen also asks the Court to exclude Dew because of his alleged lack of qualifications. (Shaked Moving Br. at 9–10.) The Court declines to address this argument because Dew supports Shaked's opinion, has no independent opinion, and Janssen has asked this Court to posit Dew's exclusion on Shaked's exclusion.
- 6 When applying the Rank Correlation Significance Test, Shaked calculated a correlation of 0.235 and a t-value of 4.212 for the correlation between a change in total compensation and average annual prescription; he also calculated a correlation of 0.406 and a t-value of 31.944 for the correlation between a change in marketing contacts and OL prescriptions. (Shaked Report ¶¶ 89, 119.) According to the t-score table found, the t-values for 99.995% confidence in the result is 3.97 for a data set of 200 values and 3.92 for a data set of 500 values. <https://faculty.washington.edu/heagerty/Books/Biostatistics/TABLES/t-Tables/>. As such, the Court finds that the values calculated are reliable.
- 7 Mark Wilhelm was a Key Account Director for Janssen's Western Division from 2007 and 2009. Sara Strand was a Regional Business Director for the Eastern Division from 2006 to 2011. Relators included them as witnesses with first-hand knowledge of Janssen's practices. (Smollen Reply at 1–2.)
- 8 Evans focuses on Strand's testimony that she would occasionally send OL Intelence studies to the sales force. However, Evans ignored that Strand testified that she sent OL studies with a directive to her team that the studies were for background only and could not be used on sales calls with HCPs.
- 9 Relators have asked this Court to exclude the following paragraphs of Jena's Expert Report: ¶¶ 11, 25, 27–29, 33–34, 54, 57–58, 60, 62, and 64. (Jena Moving Br. at 4–5.) Relators have also asked to exclude the following paragraphs of Jena's Expert Rebuttal Report: ¶¶ 3, 5–8, 11 (bullets 3–5), 12–17, 20, 37–40, 43–45, 52–54, 63–65, 84, 86–87, 91, 93–97, 99, 100–15, and 118–25. (*Id.* at 5.)
- 10 Relators have asked this Court to exclude “Dr. Rosenberg's testimony to the extent that it ventures beyond explanations of the disease state and the drugs themselves.” (Rosenberg Reply at 4.) Among other examples, Relators point to several examples that Rosenberg may move beyond his medical and professional expertise to opine on inadmissible points. (Rosenberg Report, ¶¶ 34, 42–46; Rosenberg Rebuttal Report, ¶¶ 7, 16; Ellerbe Decl., Ex. 27, “Rosenberg Dep.” 12:22–25, 22:5–7, 25:19–25, 29:8–20, 41:18–42:14, 90:23–92:8, 93:2–14, 134:24–135:5, ECF No. 279–7.)

2012 WL 13029519

Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court, D. New Jersey.

TRAVELERS PROPERTY CASUALTY COMPANY OF AMERICA, as subrogee of Goya Foods, Inc., Plaintiffs,

v.

HALLAM ENGINEERING & CONSTRUCTION CORPORATION, Meadowlands Fire Protection Corp., Salvatore Scoglio, P.E.; Perley-Halladay Associates, Inc.; James E. DeBarbieri Architects; James E. DeBarbieri, R.A.; ABC Corp. 1-10 (fictitious) and John Does 1-10 (fictitious), Defendants.

Civ. No. 08-0444 (WHW)

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Filed 08/16/2012

Attorneys and Law Firms

Jeffrey Warren Lorell, Robert B. Nussbaum, Saiber LLC, Florham Park, NJ, for Plaintiffs.

Michael Arthur O'Hara, Romando Tucker Zirulnik & Sherlock, East Hanover, NJ, for Defendants.

OPINION

William H. Walls, United States Senior District Judge

*1 Plaintiff Travelers Property Casualty of American (Travelers) moves to strike the expert report (Report) and opinion testimony of forensic accountants Charles S. Amodio (Amodio) and Eric A. Kreuter (Kreuter), who were hired by Defendant Hallam Engineering & Construction Corporation (Hallam). Plaintiff contends that the Report that Amodio and Kreuter authored as a team is unreliable and fails to meet the standards of [Federal Rule of Evidence 702](#). The Court heard oral argument on July 24, 2012. The motion to strike the experts' Report is granted in part and denied in part.

FACTUAL AND PROCEDURAL BACKGROUND

This is a subrogation action which arises out of a September 9, 2006 fire at a food processing facility of Goya Foods, Inc. (Goya) in Secaucus, New Jersey. Goya purchased the warehouse facility located at 650 New County Road, Secaucus, New Jersey, in 1997. In the fall of 1997, Goya began to construct a large refrigerated storage bean cooler in the warehouse to store boxes of dehydrated vegetables, beans and rice. The bean cooler was approximately 4,909 square feet in size and cooled by two refrigeration units. Hallam was engaged by Goya to inspect, maintain service, and repair and/or supply replacement parts for Goya's cooling units on a regular basis. Goya hired Meadowlands Fire Protection Corp. (Meadowlands) in late November 1997 to convert the warehouse's existing dry pipe sprinkler system to a wet pipe system and to install approximately 50 dry sprinkler heads in the bean cooler.

Years later, on September 9, 2006, a fire started in the bean cooler. As a result, Goya made an insurance claim to its insurer, Plaintiff Travelers. Plaintiff paid Goya \$3,067,112.47 for fire and smoke damage to the building, damage to Goya's inventory of food products stored therein, business interruption losses triggered by the closing of the plant, and other miscellaneous repair and cleaning expenses. On January 23, 2008, Plaintiff brought this action to recover its payment from the two parties allegedly

responsible for the fire and its spread: (1) Hallam for its negligent service of the refrigerator equipment and (2) Meadowlands for its inadequate design and installation of a fire sprinkler system that resulted in excessive fire spread.

Both Plaintiff and Defendants have engaged several experts to assess and quantify damages. Hallam engaged two different types of experts to evaluate the claims submitted by Goya: (1) fire safety engineering expert Kenneth P. Garside, P.E. (Garside) and (2) accountants Amodio and Kreuter. Plaintiff and its technical fire experts “agree completely” with the opinions and conclusions of Garside. Pl. Br. at 4. By contrast, Plaintiff contends that the Report of Amodio and Kreuter is unreliable and fails to meet the admissibility standard of [Federal Rule of Evidence 702](#). On January 12, 2012, Plaintiff filed a motion to strike the Report of Amodio and Kreuter and to bar their testimony. On July 24, 2012, the Court held a [Daubert](#) hearing.

STANDARD OF REVIEW

*2 [Rule 702 of the Federal Rules of Evidence](#), as amended in 2000 to incorporate some of the standards set in [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), 509 U.S. 579, 595 (1993), and [Kumho Tire Company, Ltd. v. Carmichael](#), 526 U.S. 137, 141 (1999), governs the admissibility of expert testimony:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[Fed. R. Evid. 702](#). The burden is on the party advancing the expert to show that the three prongs of [Rule 702](#) are met by a preponderance of the evidence. [In re Paoli Railroad Yard PCB Litigation](#), 35 F.3d at 744 ([Paoli II](#)).

The Third Circuit has explained that [Rule 702](#) “embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit.” [Schneider ex rel. Estate of Schneider v. Fried](#), 320 F.3d 396, 404 (3d Cir. 2003). Qualification refers to the requirement that the witness possess specialized expertise. The Third Circuit has interpreted this requirement liberally, holding that “a broad range of knowledge, skills, and training qualify an expert.” [In re Paoli Railroad Yard PCB Litigation](#), 916 F.2d at 855. Secondly, the testimony must be reliable; the testimony “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’; the expert must have ‘good grounds’ for his or her belief. In sum, ... an inquiry into the reliability of scientific evidence under [Rule 702](#) requires a determination as to its scientific validity.” [Paoli II](#), 35 F.3d at 742 (quoting [Daubert](#), 509 U.S. at 591-92). “This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.” [Paoli II](#), 35 F.3d at 744; [West Amer. Ins. Co. v. Jersey Cent. Power and Light Co.](#), 2008 WL 5244232, 7 (D.N.J. 2008). Finally, the third prong of [Rule 702](#) requires that the expert testimony fit the issues in the case. In other words, the expert's testimony must be relevant for purposes of the case and must assist the trier of fact. The Supreme Court explained in [Daubert](#) that “[Rule 702](#)'s helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” 509 U.S. at 591-92. *See also*, [Behrend v. Comcast Corp.](#), 655 F.3d 182, 216 (3d Cir. 2011) (under the fitness analysis, the expert's testimony must be “sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.”).

DISCUSSION

Defendant Hallam retained accountants Amodio and Kreuter to evaluate and quantify the damages claimed by Plaintiff. Amodio and Kreuter state in their Report that their opinions are based on the report of Garside, a fire safety engineering expert. Garside found that the sprinkler system designed and installed by Meadowlands was completely inadequate for the bean cooler. Garside concluded that the fire spread was excessive due to the defective sprinkler system and that the fire damage would have been greatly diminished had the sprinkler system been designed and installed properly. No party objects to the opinion of Garside.

*3 In the Report, Amodio and Kreuter attempt to quantify and allocate what percentage of loss is attributable to Hallam as opposed to Meadowlands. Plaintiff argues that this damages allocation is predicated on the experts' arbitrary and subjective judgments about how much physical damage each defendant was responsible for causing and fails to meet the reliability standard of [Federal Rule of Evidence 702](#). Plaintiff also argues that Amodio and Kreuter are not qualified to opine as to the conclusions in the Report and contend that the Report improperly invades the role of the jury rather than assisting them.

A. Amodio and Kreuter Are Qualified to Testify as Forensic Accountants.

Plaintiff does not dispute Amodio's and Kreuter's qualifications as accountants but argues that they are not qualified to opine on the loss attributable to Hallam as opposed to Meadowlands because they are not experts with respect to fire loss investigations or fire spread analysis. Pl. Br. at 21. The Court finds this argument unpersuasive because Amodio and Kreuter are not making engineering conclusions. They do not speak to the veracity of anything in the fire engineering report of Garside. Rather, they are relying upon their expertise in the area of accounting to evaluate and put a dollar amount to the damages that resulted from the fire. This is an appropriate task for forensic accountants. Amodio and Kreuter, as reflected by their respective curriculum vitae and extensive experience in the field of forensic accounting, *see* App. B & C of Report, are clearly qualified as forensic accountants who may be retained to evaluate the merit of the alleged damages.

B. Kreuter's Conclusion that Hallam is Responsible for 10-15% of Total Fire Damage Loss Is Not Reliable.

Hallam claims that it should only be liable for "expected damages," or damages due to the impact of water and smoke that would have been sustained even if the sprinkler system had worked properly. Pl. Br. at 7-9. In Section V of the Report, entitled "Excess Damages Caused by Inadequate Design of Fire Protection Sprinkler System Not the Fault of Hallam," Kreuter attempts to quantify what percentage of the total loss constitutes "expected damages."

Kreuter relied on the report of fire engineer Garside in determining the amount of damages that would have been avoided had the sprinklers functioned properly. One of Garside's key findings was that "[t]he subject sprinkler system was inadequate to properly control and quench the fire that initiated on 9/9/06. Had the system been properly configured and designed, **the subject fire start would have been extinguished in the incipient stage to mitigate excessive damage** to the bean cooler and extensive building smoke damage as sustained." Garside Report at 6 (emphasis added). Upon consulting the Merriam-Webster dictionary for the definition of "incipient," Kreuter determined that the fire damage to the bean cooler room would have been "minimal" had the sprinklers functioned. Kreuter Dep. Tr. 63:2-9; Pl. Br. at 9. Kreuter then decided, based on his personal interpretation of the facts that 10-15% allocation of total damages to Hallam was reasonable. Kreuter Dep. Tr. 70:9-11; Pl. Br. at 8.

The Court finds that Kreuter's percentage allocation conclusion fails to satisfy the reliability standard of [Rule 702](#). While absolute certainty in damages calculations is not necessary in allowing a jury to consider an expert's damages calculations, it is well established that damages calculations must be based upon some reasonable basis with reasonable certainty. *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (the "expert's opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation."); *Daubert*, 509 U.S. at 590 ("the expert must have 'good grounds' for his or her belief."); *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (expert testimony relating to economic damages cannot be based on assumptions lacking any factual foundation in the record).

*4 Kreuter's leap from Garside's report to his percentage allocation conclusion lacks sufficient scientific or other reasonable basis. Kreuter does not discuss industry standards nor processes in formulating his opinion. At his deposition and at the Daubert hearing, he could not explain why he was able to apportion 10-15% of the loss to Hallam and why that percentage allocation should not be closer to, for example, 5% or 20%. Def. Br. 12-13; Daubert Tr. 24-25, 44, 51. Instead, Kreuter simply reiterated that his opinions were based on his generalized experience and knowledge. Def. Br. 12-13; Daubert Tr. 24-25. But the Third Circuit has established that qualifications alone and subjective belief are not enough to establish the requisite level of reliability. See Murray v. Marina Dist. Devel. Co., 311 Fed.Appx. 521, 524 (3d Cir. 2008) (affirming district court's decision to disallow expert testimony where expert (1) did not cite to any established industry standards for his opinions and (2) did not provide any explanation that could be tested or subjected to peer review as to how he reached his opinions on grounds that the expert's testimony amounted to no more than "subjective belief or unsupported speculation" rather than "methods or procedures of science."); Paoli II, 35 F.3d at 742 (holding that an expert's opinion cannot be based upon subjective belief or unsupported speculation and he must have "good grounds" for his belief); FedEx Ground Package Sys., Inc. v. Applications Int'l Corp., 695 F. Supp. 2d 216, 223 (W.D. Pa. 2010) (stating that an expert's "qualifications alone are simply not enough to establish the requisite level of reliability required by the Federal Rules and Daubert"). While it is undisputed that the sprinkler system installed by Meadowlands was incapable of suppressing the fire and the prolonged duration of the fire resulted in materially more damage to the space outside the bean cooler, the record fails to reveal a method that would have enabled Kreuter to evaluate the precise quantitative effect on the damages resulting from the prolonged fire. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (affirming district court's exclusion of expert testimony where the district court concluded that there was too great an analytical gap between the data and the opinion and "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

C. Kreuter's Analysis Regarding Goya's Temporary Labor Costs Is Not Reliable.

In Section V-I of the Report, entitled "Temporary and Goya Labor Cost Allowance," Kreuter quantifies what portion of the labor costs associated with the clean up of the fire should fall under "expected damages."¹ Report at 6. Kreuter concludes that "[o]f the total, (\$85,791), it is deemed reasonable to allow 10% of such costs as a valid claim (\$8,579) as described earlier this report." Id.

This conclusion fails to meet the reliability standard of Rule 702. Kreuter arrived at this conclusion by multiplying his 10-15% allocation determination discussed above to every category of Goya's fire loss—in this case, labor costs. Since Kreuter's initial 10-15% damages allocation lacked reasonable grounds and reasonable certainty, it follows that his conclusion with respect to labor costs deriving from his initial percentage allocation conclusion is also suspect. Kreuter's conclusions are all the more questionable given that, earlier in the Report, Amodio states that he cannot opine as to the claimed labor costs for Goya's employees (totaling \$62,738) and for Cornerstone's workforce (totaling \$23,053)²: "We have not been afforded an opportunity to analyze the combined claimed labor costs, thus, we are unable to opine whether the labor costs are normal or additional costs related to the fire event." Id. at 7. Given that Amodio claims that neither he nor Kreuter had enough information to evaluate whether the labor cost claims were normal or not, the Court finds that Kreuter did not have a reliable basis upon which to determine that only 10% of the labor cost claims constitute "expected damages."

D. Kreuter's Analysis Regarding Allocation of Lost Inventory Is Not Reliable

In Section V-J of the Report, entitled "Personal Property (Inventory) Allowance," Kreuter and Amodio attempt to formulate that portion of the lost inventory that should be attributable to Hallam. Based upon (1) a comparison of the size of the bean cooler (4,909 square feet) to the footprint of the warehouse building (approximately 70,000 square feet) and (2) their assumption that, had the sprinklers functioned correctly, most of the fire damage would have been contained to the bean cooler, Amodio and

Kreuter state that “[f]ollowing a conservative approach, we can reasonably estimate that perhaps 25% of the total value of food products claimed to have been damaged in the fire was stored in the [bean cooler].” Id. at 18.

*5 There is a logical gap between the data available to Amodio and Kreuter and the conclusion that 25% of the claimed inventory loss by Goya should be considered “expected damages.” It would seem that an essential part of this determination would be an investigation of how many foodstuffs were located outside the bean cooler versus inside the bean cooler at the time of the fire. But Amodio and Kreuter write in the Report that their records did not make this information available. Id. at 17. The Court finds that Amodio and Kreuter could not have allocated what portion of the lost inventory should be attributable to Hallam with reasonable certainty without knowing, or having a reasonably reliable estimate based on good grounds, of this variable. As such, the Court finds that Amodio's and Kreuter's conclusion with respect to Goya's lost inventory claim is unreliable and inadmissible.

E. Kreuter's Analysis Regarding the Length of Goya's Business Interruption Is Not Reliable

Section V-K of the Report, entitled “Business Income Loss Allowance,” assesses the length of business interruption that Goya would have suffered had the sprinklers functioned properly. Without providing any methodology behind their conclusion, Kreuter and Amodio state that the length of compensable business interruption suffered by Goya should be three weeks, consisting of “one week to deal with the fire and two weeks for planning and restoration for a total of three weeks lost income.” Id. at 18.

The Court finds that this conclusions fails to be meet the reliability standard of [Rule 702](#). During their depositions, both Amodio and Kreuter testified that they were not familiar with how long it took similar manufacturing facilities to recover from a fire, or how long it takes to remove pallets of burnt product or a metal rack system after a fire, or how long it takes to replace a refrigeration system or sprinklers after a fire. Amodio Dep. Tr. 61-64; Kreuter Dep. Tr. 99-100. In fact, Amodio admitted at his deposition that he could not state with any professional certainty that the business interruption period should be three, four or six weeks:

Q: When you selected the ... three weeks, you didn't have any hard data of any sort to base that estimate on, did you?

A: No hard data other than the report prepared by Mr. Garside regarding the fire and the sprinkler system.

Q: Would it be fair to say that you cannot say to any reasonable degree of professional certainty that the downtime for this plant after a fire with the proper sprinkler system would be three weeks as opposed to four weeks as opposed to four and half weeks. Right?

A: Correct.

Q: You can't say with any professional certainty whether it's four and a half weeks or six weeks.

A: Correct.

Amodio Dep. Tr. 63:25-64:18. (emphasis added.)

The Report, depositions, and further probing at the Daubert hearing fail to convince the Court that this conclusion rests on “good ground” with “reasonable certainty” as the Third Circuit has required in Paoli. As such, Plaintiff's motion to strike this portion of the Report is granted and Amodio's and Kreuter's testimony regarding this conclusion is barred.

F. Amodio's Analysis on Goya's Business Income Claim Shall Be Admitted and Subject to Cross-Examination.

In Section IV-A of the Report, Amodio assesses the report of Plaintiff's expert Morgan, Johnson Carpetner & Company, CPA's (MJC), who Plaintiff engaged to quantify damages. Amodio's primary concern with MJC's report deals with the firm's treatment of Goya's business income loss. Amodio claims that Goya's claim for damages relating to lost sales is suspect because of a "potential failure to mitigate its damages." Report at 5. Specifically, Amodio notes that, based on the documents he examined, MJC did not explore the possibility that Goya could have filled lost orders at alternate Goya distribution facilities. *Id.* Amodio notes that Goya did not appear to have made an attempt to redirect incoming shipments of raw materials to its other capable plants so as to minimize the potential impact of additional "unsatisfied demand," which is Goya's terminology for situations where they were unable to fill orders due to lack of available product. *Id.* at 3.

*6 The Court finds that this portion of the Report is admissible and satisfies the requirements of Rule 702. The Third Circuit has stated that "there may be some circumstances where one's training and experience will provide an adequate foundation to admit an opinion and furnish the necessary reliability to allow a jury to consider it." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158; *West American Ins. Co. v. Jersey Cent. Power & Light Co.*, No. 03-cv-6161, 2008 WL 5244232, *8 (D.N.J. Dec. 15, 2008). Here, Amodio is relying upon his 10 years of experience as a forensic accountant to evaluate and critique the report of another accountant hired by the Plaintiff. Amodio's professional experience provides an adequate foundation for him to consider and point out areas of oversight—such as Goya's failure to attempt to mitigate damages—by Plaintiff's expert MJC. Plaintiff will have the opportunity to challenge Amodio's conclusion through cross-examination and any presentation of contrary evidence at trial.

Having determined that this section of the Report satisfies the reliability standard of Rule 702, the Court also finds that it satisfies the "fit" requirement of the Rule. The "fit" requirement is a question of whether "the expert's testimony [is] relevant for the purposes of the case and [will] assist the trier of fact." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). A fundamental issue for the jury will be how to allocate responsibility for and quantify damages resulting from the fire in the bean cooler. The deliberation process will involve assessing the accounting reports of the Plaintiff's experts. Amodio's assessment of MJC's report will help the jury better understand issues in lost sales calculations and also aid the jury in making a more informed decision on how much weight to give to the report. Amodio's evaluation in this section of the Report will be helpful to the jury when it deliberates the quantification of damages.

CONCLUSION

The Court finds that Amodio's and Kreuter's 10-15% damages allocation conclusion fails to satisfy the reliability standard of Rule 702 and is inadmissible. The experts' conclusions regarding Goya's business income loss, labor costs, lost inventory and business interruption damages also lack reasonable basis and reasonable certainty and, as such, are inadmissible. Section IV-A of the Report dealing with Goya's potential mitigation of lost sales satisfies the requirements of Rule 702 and is admissible.

All Citations

Not Reported in Fed. Supp., 2012 WL 13029519

Footnotes

- 1 As discussed in the previous section, Kreuter defines "expected damages" as damages that would have occurred had the sprinkler system functioned properly, or "damages sustained due to the fire itself and subsequently-related impact of water and smoke." A&K Report at 7-8.

2 The clean up labor was supplied by Goya's employees but was also supplemented by Goya's subcontractor Cornerstone.

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2013 WL 12164773

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NOT FOR PUBLICATION

United States District Court, D. New Jersey.

ALTANA PHARMA AG and Wyeth, Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC., et al., Defendants.

Civil Action No. 04–2355 (JLL)

I

Signed 05/14/2013

Attorneys and Law Firms

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OPINION

JOSE L. LINARES, U.S. DISTRICT JUDGE

*1 This matter comes before the Court by way of Plaintiffs Altana Pharma AG and Wyeth (collectively “Plaintiffs”)’s motion *in limine* seeking to exclude the following evidence pursuant to Fed. R. Evid. 702 and 403: (1) Dr. Ryan Sullivan’s opinion on bundling;¹ (2) portions of Dr. Jeffrey Leitzinger’s opinions concerning Plaintiffs’ lost profits claims; (3) Dr. James Malackowski and Dr. Frank Bernatowicz’s respective opinions on reasonable royalties; and (4) Dr. Mitchell Schubert’s opinion regarding the interchangeability of various proton-pump inhibitors (“PPI”)s. For the reasons set forth below, Plaintiffs’ motion is **denied** in its entirety.

I. BACKGROUND

Because the Court has extensively set forth the facts of this case in numerous summary judgment opinions, only those facts specifically pertinent to the instant motion are discussed below.

A. Dr. Jeffrey Leitzinger’s Opinions Concerning Plaintiffs’ Lost Profit Claims

Dr. Leitzinger is an economist whom Defendant Sun asked to review the opinions of Plaintiffs’ expert, Dr. Christopher Vellturo, regarding Plaintiffs’ entitlement to lost profits as a result of Sun’s infringement of the ‘579 patent. In Dr. Leitzinger’s opinion, “Dr. Vellturo’s calculation of lost profit damages attributable to Sun fundamentally errs in its failure to properly assess losses that were reasonably caused by Sun’s infringement.” (CM/ECF No. 1274–4 at 4, ¶ 7.) Specifically, Dr. Leitzinger opines that Dr. Vellturo’s analysis is flawed because it ignores that Teva’s infringing generic and Wyeth’s own generic were already in the marketplace at the time that Sun launched its product. (*Id.* at 9, ¶ 72.) Consequently, Dr. Leitzinger opines that the lost profits Dr. Vellturo “attributes to Sun are vastly overstated.” (*Id.* at 4, ¶ 7.) Additionally, Dr. Leitzinger asserts that “Dr. Vellturo’s calculations of overall lost profit amounts ... are based upon inflated projections of **Protonix** sales volumes and prices that would have existed but for infringement.” (*Id.* at 4–5, ¶ 7.)

B. Dr. James Malackowski and Frank Bernatowicz Opinions Concerning Plaintiffs Reasonable Royalty Claims

Dr. Malackowski and Dr. Bernatowicz are, respectively, Defendants Teva and Sun's reasonable royalty experts. Both experts critique Dr. Vellturo's opinion on reasonable royalties, and base their opinions, in large part, on their review of pantoprazole licensing agreements.

C. Dr. Schubert's Opinion Regarding the Interchangeability of Various PPIs

Dr. Schubert is a physician specializing in gastroenterology. He has served as Chief of Gastroenterology at the McGuire Veterans Affairs Medical Center since 1999, and treats approximately 50–60 patients per week in his clinical practice. (See CM/ECF No. 1316–6 at 3, ¶ 6.) Dr. Schubert is also a professor at Virginia Commonwealth University's Medical College, where he teaches gastroenterology to medical students, interns, residents, fellows, and other gastroenterologists. (See CM/ECF No. 1316 at 21.) He also serves as associate-editor of two gastroenterology-related publications—*Digestive Diseases & Sciences* and *Current Opinion in Gastroenterology*. (CM/ECF No. 1316–6 at 2, ¶ 7.)

*2 Teva and Sun retained Dr. Schubert to render an opinion on the interchangeability of PPIs and factors that motivate physicians' PPI-prescribing decisions. (*Id.* at 4, ¶ 10.) Dr. Schubert is expected to testify that when generic pantoprazole entered the market in December 2007, it was already known that “PPIs are clinically equivalent and therapeutically interchangeable. (*Id.* ¶ 12.) Dr. Schubert is also expected to testify that “a predominant factor” in a physician's prescription choice is “[c]lost to the patient (and how it is controlled by [third-party payers].” (*Id.* ¶ 13.) Dr. Schubert bases his conclusions on his training and experience, and his review of medical literature. (See generally *id.*)

II. LEGAL STANDARD

A. General Standard for Deciding Motions *In Limine*²

District Courts have broad discretion “in determining the admissibility of evidence under the Federal Rules.” See *United States v. Abel*, 469 U.S. 45, 54 (1984). Courts may exercise this discretion to rule on motions *in limine* “to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions.” *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir. 1990). It is generally appropriate, however, for courts to reserve judgment on a motion *in limine* until trial. See, e.g., *Kraemer v. Franklin & Marshall College*, No. 95-0020, 1995 U.S. Dist. LEXIS 17093, at *3-4 (E.D. Pa. Nov. 15, 1995) (“The Court declines to rule on whether to exclude ... testimony before it has been placed into a specific context at trial.”); see also *Hawthorne Partners v. AT&T Technologies, Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993) (“This court has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds”).

B. Standard for Admissibility of Expert Testimony

The admissibility of expert testimony is governed by Fed. R. Evid. 702, which provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case.

The Third Circuit has held that Rule 702 “embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit.” *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). To satisfy the qualification requirement, a witness must “possess specialized expertise.” *Id.* at 404. This requirement is interpreted liberally; “a broad range of knowledge, skills, and training qualify an expert as such.” *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). To be reliable, there must be a “link between the facts [underlying the expert's opinion] and the conclusion.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012); *see also Kumho Tire*, 526 U.S. 137, 157 (1999) (observing that courts are not required “to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert”) (internal citations omitted). Finally, the question as to whether an expert's proffered testimony is a fit is one of relevance that requires the court to determine whether the proffered testimony “will aid the jury in resolving a factual dispute.” *See Lauria v. AMTRAK*, 145 F.3d 593, 599-600 (3d Cir. 1998) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 591 (1993)).

*3 It is well settled that district courts must serve a “gatekeeping function” to ensure that an expert's testimony satisfies the requirements of Rule 702. *See, e.g., Daubert*, 509 U.S. at 592–95; *Kumho Tire Co.*, 526 U.S. at 141. In performing this function, courts must be mindful that Rule 702 “has a liberal policy of admissibility.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). Indeed, the Third Circuit has observed that the standard for admissibility “is not intended to be a high one.” *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000). The proponent of expert testimony need not prove that its expert is correct, but that the expert's “opinion is based on valid reasoning and a reliable methodology.” *Id.* at 146. “The analysis of conclusions themselves is for the trier of fact when the expert is subject to cross-examination. *Id.*; *see also ZF Meritor*, 696 F.3d at 290 (holding that mere existence of evidence in the record that contradicted expert's conclusion was no basis to exclude expert's testimony).

C. Standard for Exclusion of Testimony under Rule 403

Even if relevant, expert testimony may be excluded under Rule 403. *See, e.g., Daubert*, 509 U.S. at 595. Rule 403 allows district courts to exclude relevant evidence “if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. “Pretrial Rule 403 exclusions should rarely be granted.” *In re Paoli R. Yard PCB Litig.*, 916 F.2d 829, 859-60 (3d Cir. 1990) (“In sum, we hold that in order to exclude evidence under Rule 403 at the pretrial stage, a court must have a record complete enough on the point at issue to be considered a virtual surrogate for a trial record.”). *Id.* at 859.

III. DISCUSSION

The Court will now turn to the merits of Plaintiffs' motion seeking to exclude (1) Dr. Leitzinger's opinions concerning Plaintiffs' lost profits claims; (2) Dr. James Malackowski and Dr. Frank Bernatowicz's respective opinions on reasonable royalties; and (3) Dr. Mitchell Schubert's opinion regarding the interchangeability of various PPIs.

1. Plaintiffs' Motion as to Dr. Leitzinger

Plaintiffs seek to preclude Dr. Leitzinger from testifying about (1) his lost profits calculations premised on the notion that all of Sun's sales would have been made by Wyeth's own generic and (2) his critique of Dr. Vellturo's analysis of the market demand for *Protonix*.

a. Admissibility of Dr. Leitzinger's Lost Profits Calculations Attributing Plaintiffs' Lost Profits to Sales Lost to Wyeth's Own Generic

Plaintiffs object to the admissibility of Dr. Leitzinger's lost profit calculations on the bases that Dr. Leitzinger (1) has not sponsored his calculations as his own opinion and (2) has conceded that his methodology in performing these calculations is inconsistent with economic principles. (*See* CM/ECF No. 1265 at 21-24.) Specifically, Plaintiffs argue that Dr. Leitzinger's lost profit calculations are inadmissible because he has not sponsored said calculations as the lost profit damages “that could or should or are attributable to Sun.” (*Id.* at 22.)

Sun refutes the accuracy of Plaintiffs' assertion that Dr. Leitzinger does not sponsor his calculations relating to lost profits as his own opinion. (CM/ECF No. 1316 at 10.) According to Sun, "Plaintiffs' assertion that Dr. Leitzinger 'does not sponsor' his rebuttal calculation is unfounded as the calculation assumes a but-for world that Dr. Vellturo never acknowledges – a but-for world that has both brand and generic pantoprazole on the market." (*Id.*) Sun further asserts that "Dr. Leitzinger did not make this calculation because he believes that 100% of Sun's sales would have been interchangeable to Wyeth's AG in the proper but-for world," but "as a rebuttal calculation to demonstrate the significant economic impact of Dr. Vellturo's more lucrative selection of a but-for world that contains only the brand pantoprazole product, *Protonix*." (*Id.* at 11.)

*4 As this Court has observed in prior summary judgment decisions in connection with this case, determining how the market would have looked but for Defendants' infringement is a factual question for the jury. Fundamental fairness dictates that Sun be entitled to challenge Dr. Vellturo's opinions on lost profit damages by eliciting testimony from Dr. Leitzinger pertaining to his own lost profit calculations. Plaintiffs may attempt to expose flaws in Dr. Leitzinger's calculations at trial. The mere existence of any such flaws, however, does not warrant exclusion of references to Dr. Leitzinger's lost profit calculations at this time. *See, e.g., Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414-15 (3d Cir. 2002) ("A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination); *see also United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.") (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)).

b. Admissibility of Dr. Leitzinger's Critique of Dr. Vellturo's Analysis of the Market Demand for *Protonix*

Dr. Vellturo's lost profits analysis is based on the four factors set forth in *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). These *Panduit* factors are: "(1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) [] manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit [the patent owner] would have made." *Panduit*, 575 F.2d at 1156. In Dr. Leitzinger's opinion, Dr. Vellturo's analysis of the first *Panduit* factor – demand for patented product – is flawed because it fails to distinguish between demand for the patented product and demand for the patented technology. According to Dr. Leitzinger, "marketing and low prices were the driving forces behind sales of *Protonix* and not safety or efficacy tied to the '579 patent." (CM/ECF No. 1265-1 at 283, ¶ 29.)

Plaintiffs argue that Dr. Leitzinger's critique of Dr. Vellturo's analysis of the first *Panduit* factor is "based on a fundamental misapplication of controlling Federal Circuit law." (CM/ECF No. 1265 at 24.) To support this argument, Plaintiffs rely primarily on *DePuy Spine, Inc. v. Medtronic Sofamor Danek*, 567 F.3d 1314 (Fed. Cir. 2009), a case in which the Federal Circuit rejected the notion that the "requisite demand under the first *Panduit* factor is demand for the specific feature ... that distinguishes the patented product from a noninfringing substitute, not simply demand for the patented product." *DePuy*, 567 F.3d at 1330. The *DePuy* court made clear that the first *Panduit* fact "does not require any allocation of consumer demand among the various limitations recited in a patent claim.... [but] simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.'" *Id.* (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548-49 (Fed. Cir. 1995) (en banc)).

According to Plaintiff's, Dr. Leitzinger's assertion "that demand for the patented product under *Panduit* can be demonstrated only where the demand for *Protonix* can be linked to a demand for the claimed feature (the patented compound) that makes *Protonix* an improvement over other proton-pump inhibitors ... available in the market" is contrary to Federal Circuit precedent. (*Id.*) Sun, on the other hand, rejects Plaintiff's characterization of Dr. Leitzinger's opinion as suggesting that establishing a demand for *Protonix* requires proof of demand for the patented compound that makes *Protonix* more desirable than other PPIs. (See CM/ECF No. 1316 at 8.) Specifically, Sun maintains that Dr. Leitzinger's "makes no such statement and does no such thing," but merely "provides an opinion as demand as affected by the relevant economic factors, which include the properties of the pantoprazole compound itself." (*Id.*)

*5 Plaintiff's argument fails to persuade this Court to exclude Dr. Leitzinger's critique of Dr. Vellturo's opinion for two reasons. First, even if this Court were to accept the correctness of Plaintiff's interpretation of *DePuy* as holding that demand for the patented product "does not require consideration of the basis of that demand," (see CM/ECF No. 1265 at 33), *DePuy* does not categorically prohibit a jury from considering the basis underlying the demand for a patented product for the purpose of determining the extent to which such demand exists. Second, Dr. Vellturo has opinion that "there is a clear nexus between the claimed inventions of the '579 patent and the success' of *Protonix*, Wyeth's own generic, and Teva and Sun's generic pantoprazole. (CM/ECF N. 1316-2 ¶ 136.) Thus, it is appropriate to admit Dr. Leitzinger's rebuttal opinion concerning the extent to which demand for the claimed inventions of '579 patent drove demand for *Protonix*, as said opinion will assist the trier of fact in understanding extent to which Vellturo has established that such a demand existed.

2. Plaintiff's Motion as to Dr. Malackowski and Dr. Bernatowicz

There is no dispute that the minimum amount of damages to which Plaintiffs are entitled is a reasonable royalty. see 35 U.S.C. & 284; *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1583 (Fed. Cir. 1983) ("A reasonable royalty ... is ... the floor below which damages shall not fall."). In their respective analyses, Dr. Malackowski and Dr. Bernatowicz apply the hypothetical negotiation framework set forth in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970). In so doing, both experts rely on actual pantoprazole license negotiated by plaintiffs. (see CM/ECF No. 1316-13 ¶¶ 20-21, 39, 45; CM/ECF No. 1309-2 at 35, ¶ 11.3.15.)

Plaintiffs argue that Dr. Malackowski and Dr. Bernatowicz's respective opinions on reasonable royalties are inadmissible because the licensing agreements these experts reviewed "are not sufficiently comparable to the hypothetical licenses to the '579 patent that Plaintiffs would negotiate with Teva and Sun." (CM/ECF No. 1265 at 36.) Specifically, Plaintiffs argue that "each of the license on which Mr. Bernatowicz and Mr. Malackowski rely have critical and disqualifying—differences in scope, time, geography, and economic circumstances to the hypothetical negotiations in the case." (CM/ECF No. *Id.* at 31.)

Plaintiffs' argument does not compel this court to exclude either Dr. Malackowski or Dr. Bernatowicz's opinions at this time. The extent to which the licenses upon which these experts relied render their opinions inaccurate is a question for the jury. Indeed, the Federal Circuit has recently affirmed that disagreement over an expert's reliance on license agreement as benchmarks for determining a reasonable royalty in a patent infringement case "go to the weight to be afforded the testimony and not its admissibility." *ActiveVideo Networks, Inc. v. Verizon Communs., Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012) ("The degree of comparability of the ... license agreements as well as any failure on the part of [the patentee's] expert to control for certain variables are factual issues best addressed by cross examination and not by exclusion."); see also *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 854 (Fed. Cir. 2010) (holding that a party's quarrel with the facts the damages expert used go to the weight, not admissibility, of the expert's opinion). Accordingly, the Court will not exclude these experts' respective opinions based on their reliance on licensing agreements which Plaintiffs contend are not instructive on the issue of reasonable royalties. Nevertheless, Plaintiffs are free to attempt to expose the flaws they believe exist in Dr. Malackowski and Bernatowicz's respective analyses at trial.

3. Plaintiffs' Motion as to Dr. Schubert

Plaintiffs argue that Dr. Schubert's opinions are inadmissible because "they are based entirely on his own views of the broader community of PPI—Prescribing Physician." (CM/ECF No. 1265 at 48.) Specifically, Plaintiffs argue that Dr. Schubert's opinions are inadmissible because he did not "study physician preference, prescribing patterns, or switching habits with regard to PPIs." (*Id.*) Plaintiffs also maintain that Dr. Schubert's opinions should be excluded because they ignore "conflicting views as to the safety of certain PPI alternatives to *Protonix*." (*Id.* at 51.)

*6 It is well settled that an expert may base his opinions on his experience in his specialized field. See, e.g., *Schneider*, 320 F.3d at 399-400 (holding that Magistrate Judge abused discretion in excluding experts' testimony regarding medical standard of care where testimony was based on "considerable professional experience" and knowledge of the "standard of care in the

medical field”); *see also* *Ellison v. United States*, 753 F. Supp. 2d 468, 485 (E.D. Pa 2010) (“The Court notes, as an initial matter, that the third Circuit recognized in *Schneider* that a standard of care opinion may be reliable even in the absence of medical literature on point.”); *Forest Labs., Inc. v. Ivex Pharms., Inc.*, 237 F.R.D. 106, 111 (D. Del. 2006) (overruling objection to expert’s opinion regarding prescribing habits of psychiatrists because opinion was based on expert’s “experience in writing prescriptions himself, as well as supervising others who write prescriptions”).

In light of Dr. Schubert’s experiences as a practicing gastroenterologist, teacher of gastroenterology, and associate-editor of two gastroenterology-related publications, the Court is satisfied that Dr. Schubert is qualified to opine on the interchangeability of PPIs and on physicians’ practices with respect to prescribing PPIs. Plaintiffs’ objection to Dr. Schubert’s opinion, at bottom, goes to the weight the jury should afford his testimony, not to its admissibility. Accordingly, this Court declines to exclude Dr. Schubert’s opinions at this time. *See, e.g., Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”); *see also Stecyk*, 295 F.3d at 414-15; *Voilas v. General Motors Corp.*, 73 F. Supp. 2d 452, 461-62 (D.N.J. 1999) (“[T]he perceived flaws in an expert’s testimony often should be treated as matters properly to be tested in the crucible of the adversarial system, not as the basis for truncating that process.”) (citations and internal quotation marks omitted).

IV. CONCLUSION

For the foregoing reasons, Plaintiffs’ motion is denied in its entirety. An appropriate order follows.

All Citations

Not Reported in Fed. Supp., 2013 WL 12164773

Footnotes

- 1 By letter dated May 1, 2013, the parties advised this Court that the portion of Plaintiff’s motion seeking to exclude Dr. Sullivan’s “bundling” opinion is moot in light of Defendants’ agreement not to enter any evidence regarding “bundling.” (CM/ECF No. 1322.) Accordingly, Plaintiffs’ motion to exclude Dr. Sullivan’s “bundling” opinion is denied as moot.
- 2 Under Federal Circuit precedent, regional circuit law governs evidentiary questions. *See, e.g., Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1371 (Fed. Cir. 2012) (“We review the district court’s decision to exclude evidence under the law of the relevant circuit.”). Accordingly, Third Circuit precedent guides this Court’s evidentiary determinations.

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United States District Court, E.D. Pennsylvania.

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION This Document Relates To:, Wisconsin, et al. v. Indivior Inc. et al.
State of Wisconsin By Attorney General Brad D. Schimel, et al. Plaintiffs,
v.
Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc., et al. Defendants.

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MEMORANDUM

[Goldberg, J.](#)

*1 Defendant Reckitt Benckiser, Inc. (“Defendant”) manufactures Suboxone, a drug commonly used to combat opioid addiction.¹ [Suboxone](#) previously came in tablet form, but in 2010, citing safety concerns, Defendant effectuated a change in the administration of this drug, switching from tablet to sublingual film. Various purchasers/consumers of [Suboxone](#) claimed that this switch was anticompetitive and solely designed to maintain Defendant's market exclusivity—a scheme known as a “product hop.” These claims have resulted in multi-district, antitrust litigation before this Court.

As discovery and class certification litigation have come to a close, the parties have raised numerous challenges under [Daubert v. Merrell Dow Pharmaceuticals](#), 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), seeking exclusion of all or selected portions of nine expert witnesses anticipated opinions. This Opinion explains my reasoning for the resolution of these motions and will hopefully set forth a clearer path towards trial.

I. FACTUAL AND PROCEDURAL BACKGROUND²

The Plaintiffs in this multi-district litigation case allege anticompetitive conduct by Defendant Reckitt Benckiser, Inc. in connection with their Suboxone product. Plaintiffs’ claims focus on a relatively new theory of antitrust liability, referred to as a “product hop,” pursuant to the unique regulatory and statutory scheme that governs the marketing and distribution of

pharmaceutical drugs. Under this theory, a pharmaceutical company makes modest reformulations to a brand-name drug prior to the expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

The Plaintiffs are comprised of a class of Direct Purchasers of [Suboxone](#) (“Direct Purchasers” or “DPPs”), a class of End Payors of [Suboxone](#) (“End Payors” or “EPPs”), and a group of States’ Attorneys General (the “States”) (collectively, “Plaintiffs”). These Plaintiffs claim that Defendant switched from a [Suboxone](#) tablet to a sublingual [Suboxone](#) film for the purpose of foreclosing generic competition. According to Plaintiffs, this switch (the “product hop”) was accompanied by Defendant disparaging the tablet through fabricated safety concerns and ultimately removing [Suboxone](#) tablets from the market just as generic [Suboxone](#) tablets were able to begin competing. Defendant is also accused of having manipulated FDA regulations to delay the entry of generic [Suboxone](#) onto the market through the filing of an unsubstantiated Citizen Petition and of “misconduct” during the shared Risk Evaluation and Mitigation Strategies (“REMS”) process. According to Plaintiffs, Defendant’s conduct foreclosed competition, thereby allowing Defendant to unlawfully maintain a monopoly in violation of Section 2 of the Sherman Act and overcharge for its [Suboxone](#) products. Defendant readily acknowledges the product switch, but strenuously responds that the switch was done for the pro-competitive purpose of marketing and selling an improved, safer, and superior product.

*2 During the pendency of Defendant’s appeal of the class certification ruling to the Third Circuit, I directed the parties to file any [Daubert](#) motions that would not be impacted by the Third Circuit’s certification decision. The parties have filed the following motions: (1) the DPPs’ Motion to Exclude Certain Opinions of Defendant’s Experts Nicholas M. Fleischer and Sheldon T. Bradshaw; (2) the States’ Motion to Exclude the Testimony of Defendant’s Expert Dolores Curtis, Ph.D.; (3) Defendant’s Omnibus Motion to Exclude Certain of the Opinions of Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot; and (4) Defendant’s Motion to Exclude Plaintiffs’ Expert Opinions Asserting or Relying upon Assertions that Alleged Reckitt Safety Messages Were “False,” “Misleading,” “Disparaging,” “Fabricated,” “Fraudulent,” “Sham,” or “Deceptive.”

II. STANDARD OF REVIEW

[Federal Rule of Evidence 702](#) provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data; (c) The testimony is the product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case

[Fed. R. Evid. 702](#). [Rule 702](#) places district courts in the role of “gatekeeper,” requiring courts to “ ‘ensure that any and all [expert] testimony...is not only relevant, but reliable.’ ” [Kumho Tire Co., Ltd. v. Carmichael](#), 526 U.S. 137, 147, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (quoting [Daubert](#), 509 U.S. at 589, 113 S.Ct. 2786). The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert’s qualifications and opinions comply with [Federal Rule of Evidence 702](#). See [Daubert](#), 509 U.S. at 592–93, 113 S.Ct. 2786 (citation omitted). [Rule 702](#) has “a liberal policy of admissibility,” [Pineda v. Ford Motor Co.](#), 520 F.3d 237, 243 (3d Cir. 2008) (quotation omitted), and “the rejection of expert testimony is the exception rather than the rule.” [Fed. R. Evid. 702](#), Advisory Comm Notes (2000). As the Court in [Daubert](#) stated: “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” 509 U.S. at 595, 113 S.Ct. 2786.

The [Daubert](#) inquiry “embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit.” [Schneider ex re. Estate of Schneider v. Fried](#), 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted).

A. Qualification

In Waldorf v. Shuta, 142 F.3d 601 (3d Cir. 1998), the United States Court of Appeals for the Third Circuit articulated the “qualification” standard for an expert:

Rule 702 requires the witness to have “specialized knowledge” regarding the area of testimony. The basis of this specialized knowledge “can be practical experience as well as academic training and credentials.”...We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony “extends to the substantive as well as the formal qualification of experts.”...However, “at a minimum, a proffered expert witness...must possess skill or knowledge greater than the average layman....”

Id. at 625 (citations omitted).

Construing this standard, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). In other words, “an expert’s qualifications should be assessed ‘liberally,’ recognizing that ‘a broad range of knowledge, skills, and training qualify an expert as such.’ ” Thomas v. CMI Terex Corp., No. 07-3597, 2009 WL 3068242, at *5 (D.N.J. Sept. 21, 2009) (quoting Paoli, 35 F.3d at 741). An expert will not be excluded “simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996). The focus, instead, is on whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter. See Buzzard v. Flagship Carwash of Port St. Lucie, Inc., 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009).

B. Reliability

*3 The reliability restriction requires that the testimony be based upon “the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’ ” and that the expert have “ ‘good grounds’ for his or her belief.” Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). In that respect, reliability mandates an examination into the expert’s conclusions in order to determine “whether [the conclusions] could reliably flow from the facts known to the expert and [the] methodology used.” In re Diet Drugs(Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig., 706 F.3d 217, 225 n.7 (3d Cir. 2013) (quoting Oddi v. Ford Motor Co., 234 F.3d 136, 146 (3d Cir. 2000) (internal quotation marks omitted)).

The Third Circuit has identified the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. Elcock v. Kmart Corp., 233 F.3d 734, 745–46 (3d Cir. 2000). Although this list of factors is lengthy, not each factor will be relevant to every reliability analysis. The “test of reliability is ‘flexible.’ ” Kumho, 526 U.S. at 141, 119 S.Ct. 1167. According to the Supreme Court, “Daubert’s list of specific factors neither necessarily nor exclusively applies to all experts.” Id. The relevance of the Daubert factors depends “on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” Id. at 150, 119 S.Ct. 1167 (internal quotation marks and citations omitted).

Importantly, the rule does not require the party proffering the expert to demonstrate the “correctness” of the expert’s opinion. Paoli, 35 F.3d at 744 (concluding that the “evidentiary requirement of reliability” amounts to a lower burden “than the merits standard of correctness”). Rather, the party need only demonstrate “by a preponderance of the evidence” that the expert’s opinion bears adequate indicia of reliability. Id. Indeed, “[a] judge will often think that an expert has good grounds to hold the opinion...even though the judge thinks the opinion otherwise incorrect.” Id. Therefore, “[t]he focus...must be solely on principles and methodology, not on the conclusions that they generate.” Daubert, 509 U.S. at 595, 113 S.Ct. 2786. “When the methodology

is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility.” *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91, 131 S.Ct. 2238, 180 L.Ed.2d 131 (2011).

C. **Fit**

The issue of fit “is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.” *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999). The standard for fitness is “not that high” but is “higher than bare relevance.” *Paoli*, 35 F.3d at 745. To determine whether an expert's testimony “fits” the proceedings, this Court asks whether it “will help the trier of fact to understand the evidence or to determine a fact in issue.” *Fed. R. Evid.* 702(a); *see also* *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 835 (3d Cir. 2020). “‘Fit’ is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.* (quoting *Daubert*, 509 U.S. at 591, 113 S.Ct. 2786). “Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*.” *Id.* (quoting *Paoli*, 35 F.3d at 743 (emphasis in original)).

III. THE DIRECT PURCHASER PLAINTIFFS’ OMNIBUS *DAUBERT* MOTION

*4 I first consider the DPPs’ *Daubert* motion to preclude certain opinions by two of Defendant's experts, Nicholas Fleischer and Sheldon Bradshaw.

A. **Opinions of Nicholas Fleischer**

The DPPs’ first challenge involves Dr. Nicholas Fleischer. In order to understand Dr. Fleischer's opinions, some context is necessary.

Plaintiffs’ antitrust case theorizes, in part, that, absent Defendant's delay during the shared REMS process,³ generic tablet manufacturers Amneal and Actavis would have brought their generic product to market sooner. In support of that theory, the DPPs offer expert Deborah Jaskot, who concludes that there were no FDA regulatory obstacles to the approval of Amneal and Actavis’ ANDAs, and that Defendant's conduct in the REMS process created the sole obstacle and delay in Amneal and Actavis’ ability to bring their generic product to market. In response, Dr. Fleischer opines on “regulatory issues involved with the review and approval of Amneal's ANDA 203136 [and] Actavis ANDA 91422.” (Decl. of Dan Chiorean (“Chiorean Decl.”), Ex.1 (“Fleischer Rep.”) ¶ 2.) Dr. Fleischer's opinions will also establish that both ANDAs had multiple deficiencies that delayed their approval.

The DPPs now seek to exclude Dr. Fleischer's opinions on two subject areas, which I discuss separately.

1. Opinion Testimony Regarding FDA Form 483

One of the key issues in this case concerns whether Defendant's conduct during the shared REMS process resulted in a delay in the approval of the Abbreviated New Drug Applications (“ANDAs”) for generic *Suboxone*. The DPPs’ regulatory expert, Deborah Jaskot, opined that if the generics’ REMS “were approved by FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame.” (Def.’s Opp’n DPPs’ Mot., Ex. 5, Report of Deborah Jaskot (“Jaskot Rep.”) ¶ 18.) Deborah Jaskot also noted that the FDA, in May 2012, had inspected the MacFarlan Smith facility—the source of Actavis’ active pharmaceutical ingredient—and did not find any compliance issues or issue any FDA Form 483s, which would have indicated Food, Drug and Cosmetic Act problems.⁴ (Def.’s Opp’n DPPs’ Mot., Ex. 6, Jaskot Rebuttal Rep. ¶ 62.)

*5 In Dr. Fleischer's responsive report, he concluded, based on an FDA internal progress log, that "Actavis' compliance deficiencies were separate from the pending REMS issues and Actavis' ANDA could not have been approved prior to their resolution on November 29, 2012." (Fleischer Rep. ¶ 130.) To rebut Ms. Jaskot's assertion about MacFarlan Smith facility, Dr. Fleischer reviewed the FDA's records regarding the May 2012 inspection and discovered that the FDA had, in fact, issued an FDA Form 483. In paragraph four of Dr. Fleischer's June 5, 2019 Supplemental Report, he stated that he "consulted with [his] Current Good Manufacturing Practice ("cGMP") associates at The Weinberg Group [Nita U. Patel and John T. LoPiccolo] who provided [an analysis] of the observations [in Form FDA 483]." (Chiorean Decl., Ex. 3, Fleischer Suppl. To Sur-Rebuttal Report ¶ 4 & n.4.) According to that Report, Dr. Fleischer concluded that the Macfarlan Smith facility faced "a combination of unverified analytical validation, untrained analysts, with potential micro contaminant issue leading to potential safety risks" that could have caused a delay in the approval of Actavis' ANDA. (*Id.* ¶ 4.) Dr. Fleischer opined that "Actavis' compliance deficiencies [at that facility] prevented the FDA from approving its ANDA prior to November 2012." (Fleischer Sur-Rebuttal Rep. ¶ 24.)

The DPPs contend that this opinion is inadmissible under Daubert because Dr. Fleischer simply took the opinions of two individuals not designated as experts and put them into his own words to "make it flow better." (Chiorean Decl., Ex. 7, Jan. 7, 2020 Dep. of Nicholas Fleischer ("Fleischer Jan. 7, 2020 Dep.") 32:4–12; 121:21–122:13.) According to the DPPs, for each of the "observations" made about deficiencies at the Macfarlan Smith facility, Dr. Fleischer merely adopted the analysis provided to him by Mr. LoPiccolo and Dr. Patel and "transcribed it as the way to get the message across about the seriousness of the observation." (*Id.* at 122:18–123:6.) The DPPs point out that Dr. Fleischer did not know what methodology Mr. LoPiccolo and Dr. Patel employed in reaching their opinions. (*Id.* at 34:19–22.) The DPPs further contend that neither Mr. LoPiccolo nor Dr. Patel submitted reports, and their opinions were rendered outside the discovery period, depriving the DPPs of the ability to test the veracity, reliability, education, experience, methodology, or process of these individuals.

The DPPs are correct that "an expert cannot simply be the mouthpiece of another expert." St. Paul Fire & Marine Ins. Co. v. Nolen Grp., Inc., No. 02-8601, 2005 WL 1168380, at *10 (E.D. Pa. May 13, 2005); see also In re: James Wilson Assocs., 965 F.2d 160, 173 (7th Cir.1992) ("[T]he judge must make sure that the expert isn't being used as a vehicle for circumventing the rule against hearsay.") Nonetheless, "[w]hile experts may not simply 'parrot' ideas of other experts," they "are permitted to rely on materials used by other experts in developing their own opinions." I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants, No. 03-4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008) (quotations omitted). Experts "may use a mix of objective data and subjective analysis from another expert to...create an admissible report," and the testifying expert's knowledge regarding the underlying facts "go[es] to the weight accorded to [that expert's] report and testimony, rather than its admissibility." *Id.* (quoting In re Wagner, No. 06-1026, 2007 WL 966010, at *4 (E.D. Pa. Mar. 29, 2007)). Indeed, under Federal Rule of Evidence 703, "an expert may rely on any facts or data 'of a type reasonably relied upon by experts in the particular field in forming opinions,' " even if those underlying facts or data are themselves inadmissible. St. Paul Fire & Marine, 2005 WL 1168380, at *9 (quoting Fed. R. Evid. 703). "Cases have recognized that an expert may rely on the work of others, but the expert must be able to testify to the veracity of that work." *Id.*; see also Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 286 F.R.D. 266, 271 (W.D. Pa. 2012) ("[I]t is well settled that one expert may rely upon another expert's opinion in formulating his own.")).

In light of the above precedent, and after review of the pertinent expert reports, I conclude that Dr. Fleischer's opinions—which are based in part on information received from others—are admissible. I disagree with the DPPs that Dr. Fleischer acted as a "mouthpiece" for his colleagues' opinions. Dr. Fleischer was presented with Ms. Jaskot's rebuttal report and was asked to provide responses to specific issues outlined in that report. (Fleischer Jan. 7, 2020 Dep. 20:1–14.) Dr. Fleischer was also asked to review the FDA Form 483 that showed problems during the inspection of the Macfarlan Smith facility. (*Id.* at 21:10–16.) Repeatedly, he testified that he made his own observations and formed his own opinions about what that FDA Form 482 demonstrated, and turned to his colleagues solely for consultation and confirmation of opinions he independently formed:

*6 • "I consulted with [Patel and LoPiccolo] only from the purpose of asking them to confirm my observations and my opinions about my review of the 482, to see if they would concur that my opinions and evaluations was similar to what they would have opined in seeing the 483." (*Id.* at 23:2–8.)

- “When I received that 483 and reviewed it, I found it to be a serious list of observations. And I sent the 483 to Dr. Patel and Mr. LoPiccolo and said—basically, I told them, I said, I think these are serious, but I would like your confirmation as to if you concur with my opinion that these are serious observations.” (*Id.* at 25:13–20.)
- “I read the 483. I had an opinion that these were serious-enough findings that could impact the FDA making a determination whether a facility was in compliance or not. And that is why I went to Dr. Patel and Mr. LoPiccolo, to confirm my observations that they would agree that they were of a serious nature.” (*Id.* at 28:13–21.)
- “As I said, I’m not repeating, I’m taking [Patel and LoPiccolo’s] opinions and editing them into my words....[The Supplemental Sur-Rebuttal Report is] not a conduit of [Patel’s and LoPiccolo’s] opinions. It is a—taking their opinions and putting them into the words that I wanted to state based on my analysis of those observations.” (*Id.* at 32:1–12.)
- “I did not supervise [Patel and LoPiccolo]. I just sent them the 483 and asked them basically, what I’ve been saying all along, ‘do you concur with my opinion that these are serious observations.’...[T]heir main responsibility at the Weinberg Group is dealing with GMP-type issues, almost on a day-to-day basis, which I don’t do on a day-to-day basis. So for that reason I said, you know, in order to confirm my opinion, I should ask them to see if they draw the same conclusions as I did.” (*Id.* at 33:2–17.)
- “I did not even mention to [Patel and LoPiccolo] what the case was or what drugs they were. I just asked them—as I stated several times before, I had said, ‘do you interpret these observations the same way I do that these are serious observations,’ without specificity as to what drugs were involved.” (*Id.* 45:1–8.)

Dr. Fleischer’s reliance on his colleagues to confirm his already-formulated conclusion does not constitute a basis for exclusion. “[A]n expert may expand his or her knowledge by consulting colleagues and journal articles. To hold otherwise would be to require scientists to develop all of their knowledge through their own clinical work or experiments. This is an unrealistic expectation and it ignores the reality of science as a collaborative process.” [Adel v. Greensprings of Vermont, Inc.](#), 363 F. Supp. 2d 683, 692 (D. Vt. 2005). “It would be strange, indeed, if the mere fact that an expert consulted with a similarly qualified colleague to test her theories rendered her conclusions *less* reliable. That [the expert] does not have a record of the exact changes [her colleague] proposed (and which were adopted) does not make her method unreliable, although it is a perfectly legitimate ground for cross-examination.” [Wolfe v. McNeil-PPC, Inc.](#), No. 07-348, 2011 WL 1673805, at *6 (E.D. Pa. May 4, 2011).

The record also reflects that Dr. Fleischer meets the liberal standard for qualification to render these opinions. He testified that cGMPs are “something that [he] encounter[s] in [his] work in helping clients with issues regarding observational findings, 483s and GMP-type issues.” (Fleischer Jan. 7, 2020 Dep. 24:8–15.) He further stated, “I even published a paper on CGMPs, so I’m very familiar with CGMPs.” (*Id.* at 128:17–19.) He has “read a lot of papers and have read guidances” to give him “an overall familiarity with what CGMPs are.” (*Id.* at 129:2–4.) Thus, standing alone, Dr. Fleischer’s opinion on the meaning of a cGMP and FDA Form 483 is admissible.⁵ Although Dr. Patel and Mr. LoPiccolo may have a greater expertise on that subject, that fact does not render Dr. Fleischer’s independent opinion subject to exclusion. See [Pineda v. Ford Motor Co.](#), 520 F.3d 237, 244 (3d Cir. 2008). (“[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” (quotations omitted)). Indeed, the fact that Dr. Fleischer confirmed that opinion with two qualified colleagues could bolster its reliability. To the extent the DPPs believe that Dr. Fleischer has no independent knowledge to support his opinions, that can be the subject of cross-examination and will go to the weight, not the admissibility of his expert report.

2. Testimony About the “Go Live Requirement” For the Generic ANDAs

*7 The DPPs’ also challenge Dr. Fleischer’s opinion on the “Go-Live” requirement for generic ANDAs. As set forth above, Plaintiffs’ expert, Deborah Jaskot, opined that if the generics’ REMS “were approved by FDA between August 22, 2012 and

September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame.” (Jaskot Rep. ¶ 18.) In rebuttal, Dr. Fleischer opined that the BTOD [Buprenorphine-containing Transmucosal product for Opioid Dependence] REMS required a website and call center that could “Go-Live”—i.e., be operational or functioning—prior to the launch of the ANDAs. However, according to Dr. Fleischer neither the website nor the call center were operational until March 5, 2013. (Fleischer Rep. ¶ 93.) He went on to explain:

94. The BPMG [Buprenorphine Products Manufacturers Group] contracted with PPD [an outside vendor] to develop the website and call center components of the REMS program. It took considerable time for the BPMG to select PPD as its “go-live” vendor. And, it took several months (from July 2012 to late December 2012) to finalize the PPD-BPMG agreement regarding the development, operation, and management of the BTOD REMS....

95. The PPD-BPMG agreement anticipated that the launch of the BTOD REMS “go-live” website and call center would occur roughly one to two months after FDA's approval of the BTOD REMS....

96. “In February 2013, the BPMG members requested that PPD expedite the timelines for launch of the call center and website ‘to occur on March 1 or as soon as the PPD develops and receives approval of material from the BPMG.’” (Affidavit of Robin Kinard ¶ 34 (quoting PPD000001718).) The BPMG and PPD eventually implemented changes so that the website and call center could be operational on March 5, 2013....

97. Robin Kinard, PPD's Senior Oversight Lead for the BTOD REMS project, even admits that “[g]iven the timing of FDA's final approval on February 22, 2013, PPD and the generic manufacturers could not realistically have completed all tasks necessary for the program's operational launch substantially sooner than the actual ‘go-live’ date of March 5, 2013.” (Affidavit of Robin Kinard ¶ 19.) 98. Regardless of the approval of the REMS, the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date. The original agreement between PPD and the BPMG also anticipated an even later “go-live” date. And importantly, the website and call center issues were not related to any other ANDA deficiency and delayed the launch date of Amneal's product independently of the other deficiencies.

(Fleischer Rep. ¶¶ 94–98.)

The DPPs claim that Dr. Fleischer is unqualified to offer an opinion on this issue. They assert that Dr. Fleischer applied no regulatory expertise, experience, analysis, or methodology, and that he admitted to possessing no education or experience in the areas of website and call center design or launch. The DPPs also contend that Dr. Fleischer's opinion is directly contradicted by Robin Kinard, the Senior Director of Risk Management at PPD, who is in charge of the website and call center launch and explained that some of the necessary “go-live” work was dependent on first getting REMS approval from the FDA.

According to Defendant, however, unrefuted evidence established that the FDA required a fully operational website and call center before any generic tablet was put into interstate commerce. (Def.'s Opp'n, Exs. 10, 11, 17.) Defendant asserts that Dr. Fleischer, who has almost forty years of experience in the drug approval realm, is qualified to provide the logical opinion that when the FDA conditions a company's product launch on a “fully operational” REMS (including a website) and call center, generic manufacturers cannot sell their products until these elements were operational. Such an opinion, according to Defendant, does not require or even relate to expertise in website and call center design or launch, as suggested by the DPPs.

*8 I agree with Defendant and find Dr. Fleischer qualified to render this opinion on the “Go-live” requirement. Daubert's focus is on whether an expert's qualifications provide a foundation for the witness to testify meaningfully on a given matter. Dr. Fleischer holds a Ph.D. in Pharmacology. (Fleischer Rep. ¶ 4.) His work “focuses on advising both brand and generic drug companies on the Food and Drug Administration's (‘FDA’) regulatory process for the approval of innovator and generic drugs, including scientific and regulatory issues relating to the submission and review of applications to the FDA, including new drug applications (‘NDA(s)’) and abbreviated new drug applications (‘ANDA(s)’).” (*Id.* ¶ 5.) He has advised clients on regulatory issues relating to the submission and review of at least 400 NDAs and ANDAs. (*Id.* ¶ 6.) Dr. Fleischer also worked at the FDA for seventeen years, most recently as the Director of the Division of Bioequivalence, Office of Generic Drugs. (*Id.* ¶ 8.) He has

“wide-ranging experience with FDA regulations, policies, and guidelines” as well as “experience with the specific procedures for filing, amending, and supplementing ANDAs filed under 21 U.S.C. § 355(j) and related statutes.” (*Id.* ¶ 14.)

Such extensive experience with the FDA regulatory process for both generic and brand drugs renders him sufficiently qualified to opine that the generics’ failure to have a live and running website and call center prior to March 5, 2013 would have, under the FDA’s regulations, precluded the generics from launching their products prior to that date. See generally *In re Flonase Antitrust Litig.*, 907 F. Supp. 2d 637, 642 (E.D. Pa. 2012) (finding that expert’s “lifelong experience in the field of food and drug regulation demonstrates that he is well-equipped to discuss the FDA’s processes for responding to citizen petitions, and that he is qualified to opine on whether a sophisticated petitioner like GSK could have reasonably expected to succeed in changing FDA policy with its petitions.”). Such an opinion does not require, as the DPPs contend, any expertise in website or call center design and launch. Indeed, Dr. Fleischer does not attempt to discuss what was required for the website and call center to “go live” or to posit that the generics’ website/call center itself was not ready. Rather, he simply relies on the undisputed fact that the generics’ website and call center were not ready to “go live” until, at the earliest March 5, 2013. (See Def.’s Opp’n, Ex. 14, Aff. of Robin Kinard (“Kinard Aff.”) ¶ 32 (“Although the BTOD REMS program was approved on February 22, 2013, the program was not operational until a number of days later...until March 5, 2013.”) He then applies his knowledge of well-settled FDA regulations to state that “the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date.” (Fleischer Rep. ¶ 98.) Such an opinion could be helpful for a jury to understand the regulatory obstacles that might have prevented the generics from launching their products.

I also find no merit to the DPPs’ argument that Dr. Fleischer’s opinion is directly contradicted by Robin Kinard, who was in charge of actually developing the website and call center. As noted above, the DPPs argue that Ms. Kinard stated that if the generics were approved earlier, the website could have gone live earlier because some of the necessary “go-live” work was dependent on first getting REMS approval from the FDA. (Def.’s Opp’n, Ex. 29, Dep. of Robin Kinard (“Kinard Dep.”) 115:1–25.) In her affidavit, however, Ms. Kinard admitted that the website and call center “were not operational until March 5, 2013.” (Kinard Aff. ¶ 32.) Indeed, she averred that the original Project Addendum for the BTOD Rems did not anticipate launch of the website and call center components until one to two months after FDA approval of the REMS program. (*Id.* ¶ 33.)

Moreover, a closer look at Ms. Kinard’s testimony reveals that she was more equivocal about the ability to go live earlier with FDA approval because she had not looked back to where the project was at the relevant time:

*9 Q. Was PPD in a position—just assume that the REMS had been approved earlier, during some earlier period of time, okay? Say the REMS had been approved by the FDA according to, well, your original timeline, at the end of September. Could you have gone live prior to March 5, 2012?

A. I feel like I cannot answer that hypothetically because I’d have to know where we were in the process of that time, what was built, what wasn’t built. I just don’t feel like I can just answer that hypothetically. But I would say, if we were approved earlier, would we have probably have gone live earlier, yes.

(Kinard Dep. 115:13–25.)

Dr. Fleischer did, in fact, look back to that earlier time and noted evidence that BPMG did not begin work on the Go-Live requirements until the summer of 2012, and the website was an ongoing issue through August 2012. (Fleischer Sur-Rebuttal Rep. ¶ 22.) He further remarked that, even on February 15, 2013—a week prior to the generics’ ANDA approval—the generics could not commit to a timeframe for completing the REMS website. (*Id.*) Based on that information, Dr. Fleischer opined that he “did not believe that the BPMG could have launched the mandatory website and call center in 1.5 weeks had Amneal and Actavis obtained ANDA approval in August or September 2012.” (*Id.*) Given the less than certain nature of Ms. Kinard’s testimony, I cannot find that it undermines Dr. Fleischer’s report, such that I would exclude this opinion under *Daubert*. To the extent that the DPPs can prove—either through Ms. Kinard’s trial testimony⁶ or otherwise—that the generics’ websites and call centers could have, in fact, been operational prior to March 5, 2013, those facts can be used on cross-examination to test the validity of Dr. Fleischer’s opinion.

B. Opinions of Sheldon Bradshaw

The DPPs next move to exclude opinions offered by Defendant's expert Sheldon Bradshaw, who Defendant offers in rebuttal to the DPPs' expert, Professor Patricia Zettler.

The DPPs' expert, Professor Zettler, opines in part that (a) Defendant's conduct during the development of the shared REMS ("SSRS") for **Suboxone** and generic equivalents delayed approval of the SSRS until February 2013; and (b) it was false and misleading, in violation of various laws and regulations, for Defendant to claim that **Suboxone** film was less prone to misuse and better avoided pediatric exposures than **Suboxone** tablets. Mr. Bradshaw responds that (a) Defendant did not unduly delay in commencing SSRS negotiations with BPMG [Buprenorphine Products Manufacturers Group] generic manufacturers in First Quarter 2012; (b) Defendant's negotiating positions and conduct during SSRS negotiations in 2012 were objectively reasonable under the circumstances and did not delay generic entry; and (c) Defendant's marketing claims regarding tablets and film complied with FDA promotional standards.

***10** The DPPs' challenge to Mr. Bradshaw's opinions is two-fold. First, they contend that Mr. Bradshaw impermissibly opines on the state of mind and subjective intent of Defendant and its employees during the SSRS negotiations. Second, they claim that Mr. Bradshaw improperly speculates that the FDA must have found that certain of Defendant's marketing materials complied with FDA regulations because it did not issue a Warning Letter or Untitled Letter.

1. Opinions as to Good Faith and State of Mind

The DPPs first argument challenges certain isolated portions of Mr. Bradshaw's 110-page report that project subjective motivations onto Defendant's actions. Three sets of statements are at issue:

#1 – Section III.E - “Reckitt Acted in Good Faith During SSRS Negotiations,”

214. Plaintiffs claim that Reckitt acted in bad faith by raising its various “gating” issues during SSRS negotiations with the BPMG generic manufacturers. However, the evidentiary record clearly negates such claims.

215. Robin Kinard, PPD's Senior Oversight Lead for the BTOD REMS project, was aware of Reckitt's SSRS positions and witnessed first-hand Reckitt's negotiation conduct with the BPMG generic manufacturers. She observed that: “Communications among BPMG members included debate regarding the contemplated REMS program. At times member companies disagreed regarding the merits of particular proposals. However, I do not recall any communications that I considered to be disrespectful or unprofessional. I also do not believe any participants in the BPMG meets were acting in bad faith. It is normal for manufacturers engaged in these kinds of joint projects to each advance its own positions. [sic] My observation is that each of the participants in the BPMG, including both Reckitt and the generic manufacturers, acted in good faith throughout the process.”

216. Similarly, Kellie Taylor of the FDA also recognized that neither Reckitt nor the BPMG manufacturers were clearly to blame for the breakdown of SSRS negotiations. She testified that she “was aware of there being an inability to come to a single shared system REMS agreement” among the BPMG members, but felt “the cause of that inability...could [have been] on either side of the aisle...cooperation issues in a general sense.”

217. Based on the testimonies of Ms. Kinard and Dr. Taylor, and my review of the contemporaneous documents, it is clear to me that the Reckitt's SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG's inability to create a single shared REMS system with Reckitt.

(Chiorean Decl., Ex. 4, Report of Sheldon Bradshaw (“Bradshaw Report”), ¶¶ 214–17 (internal citations omitted) (collectively “§ III.E”).)

#2 – Other References to Defendant's “Good Faith” During SSRS Negotiations

- As Reckitt began to negotiate in good faith with the Generic ANDA Holders...
- Reckitt did not mislead FDA regarding...its willingness to negotiate with the ANDA applicants in good faith.
- Throughout the SSRS negotiations, Reckitt communicated to the FDA honestly about both the progress of its negotiations with the generic manufacturers and, despite its initial disinclination to participate in SSRS negotiations, the fact that it was negotiating in good faith with the ANDA applicants once it committed to participate in SSRS negotiations and not trying to drag out the negotiations.

(*Id.* ¶¶ 115, 222, 223 (collectively the “other good faith statements”).)

#3 – Statements Regarding Subjective Motivations of the Parties

***11** • The generic manufacturers preferred to save money.

- On June 13, 2012, Reckitt—concerned how the generic manufacturers had reneged on their promise to share up front cost for the BPMG REMS—sent a memorandum...to the FDA setting forth its concerns...
- To ensure that the generic manufactures [sic] took patents [sic] safety as seriously as Reckitt itself, Reckitt requested that the BPMG commit to signing a safety mission statement.
- The uncertain nature of the law of product liability made it important to try to gain a measure of clarity regarding how legal liability and litigation costs would be apportioned.
- When Reckitt was the sole manufacturer of [buprenorphine] products the company could influence the safety protocols in the opioid addiction disease space.

(*Id.* ¶¶ 119, 162, 167, 204, 208 (collectively, the “subjective motivation statements”).)

The DPPs now contend that these state of mind and intent opinions are inadmissible because, as an expert, Mr. Bradshaw cannot offer testimony regarding someone else's state of mind. They posit that Mr. Bradshaw's reliance on Ms. Kinard's Affidavit is improper because Ms. Kinard admitted in deposition that she was not privy to much of the SSRS negotiations and could not speak to Defendant's internal discussions.

Defendant agrees with the DPPs that no expert may opine on the state of mind and subjective intent of Defendant, its employees, or any third parties. Defendant further represents that Mr. Bradshaw “will not be testifying to anyone's subjective state of mind,” and agrees that references to “good faith” are inadmissible. (Def.'s Opp'n DPPs' Mot. 18.) Nonetheless, Defendant presses that Mr. Bradshaw should be able to testify as to objective facts.

It is well settled that experts may not provide testimony concerning “the state of mind” or “culpability” of defendants, corporations, regulatory agencies, and others. [Wolfe v. McNeil-PPC, Inc.](#), 881 F. Supp. 2d 650, 661–62 (E.D. Pa. 2012); *see also* [Deutsch v. Novartis Pharms. Corp.](#), 768 F. Supp. 2d 420, 448 (S.D.N.Y. 2011) (precluding an expert witness from testifying as to pharmaceutical company's bad faith). Indeed, the question of intent constitutes a “ ‘classic jury question and not one for experts.’ ” [Robinson v. Hartzell Propeller, Inc.](#), 326 F. Supp. 2d 631, 648 (E.D. Pa. 2004) (citations omitted); *see also* [In re Rosuvastatin Calcium Patent Litig.](#), MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (“Generally, expert

witnesses are not permitted to testify regarding ‘intent, motive, or state of mind, or evidence by which such state of mind may be inferred.’ ”) (internal quotations omitted).

Here, several of Mr. Bradshaw's conclusions exceed these bounds. First, the entirety of Section III.E of his report is inadmissible because Mr. Bradshaw simply recites statements by Robin Kinard and Kellie Taylor to reach the conclusion that “Reckitt's SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG's inability to create a single shared REMS system with Reckitt.” Such an opinion regarding intent is improper. (Bradshaw Rep. ¶ 217.) While Ms. Kinard's and Ms. Taylor's observations may potentially be introduced through their individual testimony, the jury must be free to draw its own conclusion about the import of those observations.

*12 As to Mr. Bradshaw's “other good faith statements,” I also find that they are inadmissible. These statements, embedded in longer paragraphs within Mr. Bradshaw's report, impermissibly ascribe to Defendant a subjective intent to negotiate in good faith with the generic ANDA applicants.

Finally, as to the alleged “subjective motivation statements,” Mr. Bradshaw may certainly testify factually about various subjects such as potential litigation risks from safety concerns and factors that drug manufacturers consider in issuing public warnings about products. As such, wholesale exclusion of these statements is not warranted. Mr. Bradshaw cannot, however, suggest to the jury how those facts bear on the parties' subjective thought processes. Defendant has acknowledged this basic evidentiary rule and emphasized that Mr. Bradshaw's intended testimony will not delve into these subjects. Should the DPPs believe, however, that any question posed to Mr. Bradshaw at trial goes beyond permissible inquiries, they may of course object at that time.

2. Opinions About the FDA's Conclusions

The DPPs next argue that Mr. Bradshaw should not be permitted to mislead the jury about what the FDA did nor did not conclude about Defendant's marketing efforts. On this topic, Mr. Bradshaw's report states:

263. The record suggests that [the FDA's Office of Prescription Drug Promotion (“OPDP”)] was in fact specifically asked (by FDA officials reviewing Reckitt's Citizen Petition) to review at least one exemplar of Reckitt's promotional messaging....

264. Importantly, no action was taken by OPDP following this consultation (and, to date, Reckitt has not received either an untitled or warning letter concerning its marketing claims since the introduction of [Suboxone](#) Film in 2010). Based on my experience, this means that OPDP did not conclude that the materials violated FDA's advertising regulations. As Plaintiffs' expert correctly noted, when OPDP determines that promotional materials violated FDA's advertising regulations, it would send the drug sponsor a warning or untitled letter.

(Bradshaw Rep. ¶¶ 263–64 (emphasis added).)

The DPPs contend that, to the extent Mr. Bradshaw testifies that “no action was taken” by the FDA or OPDP, his opinion is false and misleading because the FDA took enforcement action against Defendant through a criminal investigation and resulting grand jury indictment based, in part, on Defendant's [Suboxone](#) marketing efforts. If Mr. Bradshaw's opinion is not excluded, the DPPs urge that a fair cross-examination of Mr. Bradshaw on his “cherry-picked account of the FDA's enforcement history” requires that evidence of the criminal investigation and indictment be admitted. (DPPs' Mot. 16.)

This argument is not the proper subject for a Daubert motion. The DPPs do not challenge Mr. Bradshaw's qualification to render this opinion, do not establish that Mr. Bradshaw's method in reaching the opinion is unreliable, and offer no challenge to the “fit” or relevance of this testimony to this case. Instead, the gist of the DPPs' motion is that *if* Defendant elicits testimony from Mr. Bradshaw on this topic, then the DPPs must be permitted to cross-examine Mr. Bradshaw on the criminal investigation and indictment to which the FDA contributed. This issue is better suited for a motion *in limine*.

*13 Any mention of criminal proceedings could be highly prejudicial. Defendant, however, should be on notice that pressing Mr. Bradshaw to state that the FDA took no action in response to Defendant's promotional materials could open the door to appropriate rebuttal.

IV. THE STATES' MOTION TO EXCLUDE DR. DOLORES CURTIS

The States have filed a Daubert motion seeking to preclude the expert testimony of Defendant's expert Dr. Dolores Curtis. Dr. Curtis is President of Curtis Analytic Partners, Inc. ("CAP"), which specializes in marketing research and provides consulting services to small, mid-size, and large organizations in the healthcare business. (States' Mot., Ex. R, Rep. of Dolores Curtis ("Curtis Rep."), ¶ 1.) Dr. Curtis's report notes that, from 2004 through 2013, CAP provided both qualitative and quantitative marketing research services to Defendant. In connection with those services, CAP ran numerous marketing studies, many of which were focused on Suboxone film and tablets, in order to gauge prescribing and user preferences. (Id. ¶¶ 16–17.) These studies were conducted with physician prescribers and non-prescribers of Suboxone, as well as patient users and non-users. (Id. ¶ 18.) Based on the results of those studies, Dr. Curtis now offers three main opinions: (1) patients and physicians prefer Suboxone film over tablets; (2) the fact that film was often less expensive than generic tablets caused patients to favor Suboxone film; and (3) Defendant's disparagement of tablets over alleged safety concerns had a "relatively minor" impact on patient and physician preferences for film.

The States seek to preclude the entirety of Dr. Curtis's proposed testimony under all three of the Daubert factors. Primarily, they assert that she is not qualified to render the opinions proposed, and also contend that Dr. Curtis cannot reliably evaluate the methodology and statistical limitations of her surveys. Finally, the States posit that Dr. Curtis's testimony fails to "fit" under Daubert because it does not assist the trier of fact.

1. Qualifications

The States first contend that Dr. Curtis is not qualified to render the opinions proposed. She is a trained school psychologist with a master's degree in education, a graduate degree in school psychology, and a doctorate in philosophy. Currently, she owns a business focused on marketing surveys. According to the States, she has no statistical analysis training or experience, was uninvolved in the formation of the CAP surveys used, relied on others to do statistical analysis, does no such statistical analysis herself, and is not qualified from any medical perspective. The States posit that nothing in this background qualifies her to testify as an expert with respect to the accuracy of the methodologies used in the surveys, the statistical accuracy of the surveys, or the characteristics of Suboxone film or other drugs.

Defendant responds that Dr. Curtis easily meets the minimal standards of qualification under Rule 702. It points out that Dr. Curtis founded CAP in 1991, and she and her company have been conducting surveys ever since. In addition to the dozens of studies for Defendant alone, CAP has conducted hundreds of studies for other clients. Dr. Curtis herself played an active role in her company's projects, discussing project design, methodologies, timing, and execution with her staff project leads and reviewing all final reports prior to transmittal. Defendant presses that Dr. Curtis's decades of experience working on consumer research studies and surveys qualifies her to evaluate and opine regarding findings in the surveys at issue here.

*14 "Qualification requires 'that the witness possess specialized expertise.'" Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008) (quoting Schneider ex re. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003)). As noted above, however, there is a liberal policy of admissibility and the Third Circuit has held that a "broad range of knowledge, skills, and training qualify an expert." Id. (quoting Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–42 (3d Cir. 1994)). The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." In re Mushroom Direct Purchaser Antitrust Litig., No. 06-620, 2015 WL 5767415, at *3 (E.D. Pa. July 29, 2015) (internal quotations omitted). "If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997) (citing Paoli, 35 F.3d at 741); see also Hammond

v. Int'l Harvester Co., 691 F.2d 646, 653 (3d Cir. 1982) (affirming admission of an expert on defective nature of farm equipment even though he had no formal schooling on the subject, but he had worked selling automotive and mechanical equipment, including agricultural equipment, and had taught automobile repair and maintenance at a high school).

I find that Dr. Curtis meets the liberal minimum qualifications to offer her statistical expert opinion on whether patients and physicians prefer Suboxone film over tablets, the impact of pricing of film and tablets on patient preference, and the impact of Defendant's safety messaging on patient and physician preferences for film. First, notwithstanding the states challenge to her lack of specialized education in statistics and the absence of a license at CAP for SPSS, (see States' Mot., Ex. D, Dep. of Dolores Curtis ("Curtis Dep."), 18:5–9, 32:4–15), Dr. Curtis's report explains:

My statistical training was during my master's and doctoral studies. At that time, I learned about and was trained on the utilization of psychological and counseling techniques requisite for evaluative purposes. On the quantitative side, I was schooled in the Statistical Package for Social Sciences ("SPSS"), as well as other survey-based statistical techniques including analysis of variance ("ANOVA"), chi-square, cross tabulations, P and F values, conjoint analysis, and univariate analyses. As such I am qualified as an expert witness.

(Curtis Rep. ¶ 19.)

At her deposition, Ms. Curtis testified that she understood how to do the statistical analysis and had training, despite the fact that she did not have broad educational background in statistics. (Curtis Dep. 132:2–21.) She admitted that she often plugged numbers into online tools, which "anybody can do," but clarified that the online tools were well-validated. (Id. at 132:22–133:25.) A jury may certainly find that, given Dr. Curtis's lack of more formal statistical training, her opinion is entitled to less weight. That factor, however, does not render her unqualified for purposes of exclusion under Daubert.

Second, as to her experience, the States press that Dr. Curtis was uninvolved in the formation of the surveys and is unqualified to offer expert opinion on the propriety of the methodologies utilized in the survey process. They posit that she did not consult with a statistician and that she personally does no statistical analysis, is not an expert in survey design or statistics, relies on the expertise of the in-house-lead of quantitative work, and only generally reviews what is suggested in research proposals. (Id. at 37:25–38:4, 39:14–19, 79:6–15.)

Dr. Curtis's report, however, suggests a broader involvement in statistical analysis. Dr. Curtis is the founder and, since 1991, has been the President of CAP. In that role, she oversees and assumes responsibility "for all qualitative and quantitative marketing research. This includes determining research design (along with [her] colleagues), establishing study leads, and assigning appropriate support staff and personal involvement in selected qualitative studies as appropriate." (Curtis Rep. 2.) She is accountable for all research aspects for studies in which she is personally involved and for studies implemented by other senior staff, and she is the key lead researcher on the majority of the qualitative studies conducted by CAP. (Id. ¶ 3.) As Dr. Curtis described her role:

*15 After initially creating the idea of the business, I put together appropriate resources and key personnel staff that would allow the company to be successful and make our services known in the pharmaceutical healthcare marketplace. I also wrote or co-wrote every proposal that left CAP, including those for Reckitt. Prior to writing proposals, I discussed the potential projects with the CAP leads who would be assigned the projects should CAP be awarded the work. These discussions covered decision-making about appropriate methodologies, timing requirements, and overall execution responsibilities. In other words, I was always aware of how each study was designed, sampled, and undertaken. I was also

regularly apprised of the status of each study. Regarding review of screeners or questionnaires for any of the quantitative studies where Dr. Piano was spearheading quantitative work, his co-lead on the study during that time, CAPs Vice President, Lori Gittleman, would address questions and/or review screeners or survey instruments as necessary. If there was a specific question or concern, I reviewed discussion outlines and survey instruments. I also typically reviewed all final reports prior to sending to end clients to ensure they met the research goals.

(States' Mot., Ex. S, Curtis Rebuttal Rep., ¶ 10.)

Finally, as to Dr. Curtis's reliance on her employees for statistical work, it is well recognized that, "[a]n expert witness is permitted to use assistants in formulating his expert opinion." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 612 (7th Cir. 2002). "Where the expert was directly involved with the research, analysis or drafting of the report, even with substantial assistance from a colleague or associate, his involvement in and knowledge of the report are matters of weight, not admissibility. Lee Valley Tools, Ltd. v. Indus. Blade Co., 288 F.R.D. 254, 266 (W.D.N.Y. 2013). Under these liberal rules of qualification, I find that Dr. Curtis indeed possesses the expertise necessary to testify as an expert on subject of consumer research studies and surveys.⁷ The arguments raised by the States are certainly fodder for cross-examination and may be fair grounds for challenging Dr. Curtis's credibility at trial. They are not, however, a basis on which to exclude her testimony entirely.

2. Reliability

The States next posit that the underlying surveys by Curtis Analytic Partners, Inc. ("CAP Reports") are fundamentally flawed, and therefore unreliable.

As set forth above, the reliability restriction requires that the testimony be based upon "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation' " and that the expert have " 'good grounds' for his or her belief." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). The rule does not require the party proffering the expert to demonstrate that the expert's assessment is correct. Paoli R.R. Yard, 35 F.3d at 744. Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion bears adequate indicia of reliability. Id. A flaw in methodology does not automatically disqualify an expert opinion; the flaw must be of such substance to create a lack of "good grounds" for the expert's conclusions. Id.

Dr. Curtis's report first provides an overview of the best practices used in a marketing research arena including: having specific goals, selecting samples that well represent the population to be studied, taking great care in matching question format and wording to the concepts being measured and the population being studied, pretesting questionnaires and procedures, using appropriate statistical analytic and reporting techniques, considering alternative data beyond a survey, using designs that balance costs with errors, training interviewers carefully on interviewing techniques and the subject matter of the survey, checking quality at each stage, maximizing cooperation or response rates within the limits of ethical treatment of human subjects, and developing and fulfilling pledges of confidentiality given to respondents. (Curtis Rep. ¶ 20 & n.6.) Dr. Curtis then goes on to discuss how the CAP studies met these best practices and explains that "[t]he research used random sampling of the target patient population and applied factor analysis, correlation, cluster analysis, Likert scales and open and closed-ended questions to address study objections." (Id. ¶¶ 21–24.) Finally, the report describes the primary research studies in detail, including the methodologies, sample sizes, relevant conclusions, and how Plaintiffs' experts misused these studies. (Id. ¶¶ 58–131.) The report also describes ten secondary supportive studies that bolster the primary studies. (Id. ¶¶ 132–47.)

*16 Dr. Curtis then offers three opinions based off of the CAP studies. First, relying on seven different studies, including "the top five highest-powered physician and patient CAP studies," she opines that patients and prescribing physicians prefer Suboxone film over tablets. (Id. ¶¶ 27, 37.) Those studies had sample sizes of up to 500 participants, spanned a time frame of 2009 to 2013, and encompassed the views of both patients and physicians. (Id. ¶¶ 37, 40.) Dr. Curtis notes that the preference

for film was largely based on two key factors, dissolution time and improved taste. (*Id.* ¶¶ 30–36.) Thereafter, Dr. Curtis looked beyond the CAP research studies and considered clinical trials, a 2012 peer-reviewed article, and surveys conducted by another marketing research firm, all of which confirmed her conclusion that Suboxone film was a “dominantly preferred first-line therapy for most opioid-dependent patients.” (*Id.* ¶¶ 154–61.)

Dr. Curtis's second opinion posits that, aside from patients’ and physicians’ preference for film, “[t]he combination of the generics’ failure to offer a substantially cheaper medication with Reckitt's cost-saving coupon program made pricing preferences point in the same direction as product preferences—toward Film.” (*Id.* ¶ 42.) Dr. Curtis cites to two January 2011 studies—one of 40 physicians and one of 300 physicians—which reflected that the most common reason for physicians prescribing the film was due to the coupon savings program. (*Id.* ¶ 47.)

Dr. Curtis's last opinion observes that “[w]hile the preference for and pricing of Film were the key drivers of treatment decisions, data indicates that any safety messaging associated with Film had a relatively minor influence on physicians’ and patients’ choice of prescriptions.” (*Id.* ¶ 49.) This opinion relies on various preference studies among both physicians and patients which gauged what factors made film more attractive over tablets, and asked study participants to rank these factors. These studies, according to Dr. Curtis, consistently found that safety features such as child-resistant packaging and ease of abuse/misuse/diversion ranked lowest among the considerations. (*Id.* ¶¶ 49–57.)

The States now identify three purported flaws in Dr. Curtis's methodology, which they claim undermines the reliability of her opinions.

a. Bias in Methodology for Selecting Patients

The States first contend that participant selection in the various CAP surveys were deliberately biased in favor of those who preferred film. They claim that Dr. Curtis admitted that, with respect to one of the surveys at issue, someone who is happy with their Suboxone tablet and has never taken film would never make it into the survey. (Curtis Dep. 256:30–275:12.) The States then note that this sampling injects bias into the results,⁸ which render them unsuitable for making inferences about overall preference for film.

*17 The States also criticize Dr. Curtis for not identifying generally accepted methods to reach her sweeping inferences about entire patient and physician populations. According to States’ expert Nicholas Jewell, Dr. Curtis “does not demonstrate for *any* of the surveys she cites why the sample sizes were chosen as they were, or how the selected group of participants compare to the population at large, or how CAP accounted for response bias.” (Jewell Rep., ¶ 60 n.87.) Moreover, States’ expert Dr. Berndt opines that Dr. Curtis provides “little to no explanation of how the responses to these surveys were processed,” including “the process of content analysis and response interpretation, thematic[] organization, employment of coding mechanisms, [and] thresholds of significance for anecdotal conclusions.” (Berndt Rebuttal Rep. ¶ 81.) Absent explanations to address these concerns, the States posit that the quantitative methods CAP actually used remain a mystery.

The States’ argument is flawed in several respects. Primarily, the States’ criticism regarding bias in the reports is leveled at only a handful of the surveys relied upon by Dr. Curtis. Assuming *arguendo* that this criticism is accurate and creates bias in those identified surveys, this deficiency does not impact the entirety of Dr. Curtis's report, which relies on more than thirty different studies. For example, several of the surveys focused solely on *physician* samplings and why physicians prescribed either film or tablets. (Curtis Rep. ¶ 27–30.) Thus, the States’ contention that a certain *consumer* population was excluded would be irrelevant to such studies. Moreover, in one major study involving a sampling of 500 consumers, 377 individuals were currently using film with past tablet experience, 89 had past film experience of at least one week, and only 34 had started on the film with no tablet experience. (Curtis Rep., App'x B.19. at 5.) Finally, to the extent the States challenge surveys for not including patients who had never tried film, such a criticism would not impact the viability of a survey that sought information about what patients

and doctors liked and did not like about tablets. (See Curtis Rep., App'x B.6, at 24 (physicians and patients did not like taste/aftertaste of tablets, the difficulty of keeping tablets under the tongue, or the fact that tablets break apart in bottles).)

More importantly, “mere technical flaws” in a survey's design or execution go to the weight to be afforded to the survey, not its admissibility. Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank of Evans City, 383 F.3d 110, 121 (3d Cir. 2004); see also Karlo v. Pittsburgh Glass Works, LLC, 849 F.3d 61, 83 (3d Cir. 2017) (“The question of whether a study's results were properly calculated or interpreted ordinarily goes to the weight of the evidence, not to its admissibility). Imperfections in the extent of a survey's universe—*i.e.*, overinclusivity or underinclusivity—generally constitute technical flaws that do not undermine a survey's admissibility. Koninklijke Philips Elecs. N.V. v. Hunt Control Sys., Inc., No. 11-3684, 2016 WL 3545529, at *6–7 (D.N.J. June 29, 2016). Stated differently, while a survey that excludes the *entire* relevant population may be so unreliable as to be inadmissible, see, e.g., Citizens Fin. Grp., 383 F.3d at 118–21 (upholding exclusion of consumer survey where interviewer polled consumers not located in the geographic area relevant to the facts of the case), a survey that is simply underinclusive or has other flaws in sampling remains admissible but subject to challenge. See, e.g., Hartle v. FirstEnergy Generation Corp., Nos. 08-1025, 08-1030, 2014 WL 1317702, at *6 (W.D. Pa. Mar. 31, 2014) (“Defendant's arguments with respect to insufficient pretesting, improper information gathering, confusion by respondents, nonrepresentative and nonrandom sampling, hypothetical bias, error rate, and inconsistent and unconventional statistical analysis are ‘technical flaws’ that go to the weight rather than admissibility of the survey.”); Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1143 (9th Cir. 1997) (finding that alleged leading questions and geographic limitation on survey respondents “go only to the weight, and not the admissibility, of the survey”); Jellibeans, Inc. v. Skating Clubs of Ga., Inc., 716 F.2d 833, 844–45 (11th Cir. 1983) (holding that “(1) poor sampling; (2) inexperienced interviewers; (3) poorly designed questions; and (4) other errors in execution” constituted “technical deficiencies” affecting the survey's weight).

*18 Here, the deficiencies identified by the States are mere “technical flaws” that go to weight not admissibility. Defendant need not demonstrate the “correctness” of Dr. Curtis's opinion at this time. Thus, the States remain free to level their challenges to Dr. Curtis's opinion during cross-examination.

b. Bias from the “Here to Help” Program

The States’ second reliability challenge contends that Dr. Curtis's opinions fail to analyze whether Defendant's “Here to Help” program biased survey responses. According to the States, many of the physicians and patients who took part in the CAP surveys were participants in Defendant's “Here to Help” support program that connected patients to doctors, reminded patients to keep appointments, educated and motivated patients, and reminded them to take their medication and refill prescriptions. After the launch of film in September 2010, Reckitt made the “Here to Help” program available only to film patients. In an internal email, James Piano—the lead statistician at CAP on whom Dr. Curtis relied—recognized that the “Here to Help” program skewed physician preferences for film over tablet.⁹ (States Mot., Ex. 24.) Yet, in her deposition, Curtis testified that she was “not a hundred percent certain of what the Here to Help program supported,” did not analyze the extent to which the “Here to Help” program might have affected Suboxone sales one way or another, and did not analyze the extent, if any, that the “Here to Help” program might have driven Suboxone preferences one way or another. (Curtis Dep. 264:4–5, 274:4–13.) Dr. Curtis also offered no opinion to assess the impact of Defendant's marketing activities for Suboxone film or tablets. (*Id.* 210:7–212:20.)

Contrary to the States’ argument, however, this factor—noted in only one of the surveys reported on by Dr. Curtis—was specifically accounted for in Dr. Curtis's report. Dr. Curtis explained that this particular study, the Suboxone Preference Shares Among Physicians, was “an online quantitative study designed to provide insight into a number of objectives.” (Curtis Rep. ¶ 58.) In a footnote, Dr. Curtis specifically commented that “[t]he study cautions that high ration of Here-to-Help enrolled physicians may increase branded over generic preference. To eliminate the effects of this preference, I will not comment on the portion of physicians who preferred branded medications over generics. However, this imbalanced preference would not affect results regarding the likes and dislikes of Film.” (*Id.* n.80.)

Thus, Dr. Curtis specifically considered the impact of the “Here-to-Help” program and opined that it only impacted brand/generic preference, not film/tablet preference. To the extent the States’ expert believes that the “Here-to Help Program” impacted the reliability of the study, it may raise this issue on cross-examination. See Alco Indus., Inc. v. Wachovia Corp., 527 F. Supp. 2d 399 (E.D. Pa. 2007) (“As long as an expert’s scientific testimony rests upon good grounds, based upon what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.”) (quotations omitted).

c. Safety Messaging

*19 Finally, the States challenge Dr. Curtis’s opinion that “any safety messaging associated with Film had relatively minor influence on physicians’ and patients’ choice of prescriptions.” (Curtis Rep. ¶ 49.) As a basis for this opinion, Dr. Curtis noted that a common question in the preference studies provided an “array of options for physicians or patients to choose from to gauge both (1) what factors made film more attractive over tablets, and (2) the relative importance of each factor.” (*Id.* ¶ 50.) Using these questions, Dr. Curtis noted that safety was rarely the leading factor and, in some studies, ranked low as a secondary concern only on physicians’ list of prescribing priorities. (*Id.* ¶¶ 50–51.) Moreover, Dr. Curtis remarked that studies documented that patients themselves were not influenced by safety claims and ranked safety factors among the lowest factors that prompted their choice of film over tablets. (*Id.* ¶ 52.) Finally, Dr. Curtis considered comments from physicians and patients on marketing surveys and observed that to the extent patients and physicians valued film’s safety profile, “it was likely for reasons entirely unrelated to marketing” and instead based on experience. (*Id.* ¶¶ 53–54.)

The States contend that the CAP online questionnaires from which Dr. Curtis derived her opinion “cannot accurately measure the influences of safety concerns because *they simply do not ask about them.*” (States’ Mot. 19–20 (quoting Berndt Rep. ¶ 81) (emphasis in original).) They assert that absent direct questions about the impact, content, or frequency of safety marketing messaging to physicians or patients, Dr. Curtis cannot reliably testify that safety was a secondary concern and not the main driver of film prescribing.

The States’ argument, however, is nothing more than a contention that there was, perhaps, a better way to gauge the impact of safety concerns on physician prescribing decisions. Such a criticism does not undermine the reliability of Dr. Curtis’s methodology or her overall opinion. Indeed, Dr. Curtis discussed surveys that asked participating physicians to rank their preferences for various film attributes, and those that involved safety concerns repeatedly ranked lower on the list. From those surveys, Dr. Curtis fairly extrapolated a finding that safety concerns did not bear heavily on prescribing decisions. To the extent the States can challenge that opinion, such challenges are more appropriately raised on cross-examination or through rebuttal experts. See AstraZeneca LP v. Tap Pharm. Prods., Inc., 444 F. Supp. 2d 278, 291 (D. Del. 2006) (admitting expert testimony on television survey despite opposing party’s objection that survey did not address certain relevant questions because the objection “can effectively be dealt with on cross-examination, and thus goes to the weight, not the admissibility of the survey.”).

3. Fit

The States’ last challenge to Dr. Curtis’s report asserts that she does not meet the “fit” requirement of Daubert. Specifically, the States argue:

Curtis’s opinions are little more than a character reference for her colleague, and offer no expert testimony as it is traditionally understood—qualitative and quantitative opinions subject to evaluation and proof. Instead, they represent an attempt to end-run inadmissible hearsay into evidence, which is wholly improper. Curtis offers no reliable testimony about the methodology utilized in the studies; her use of them despite her lack of qualifications and sound basis to do so reveal “that there is simply too great an analytical gap between the data and the opinion proffered.” Curtis’ proffered three-page opinion regarding pricing preferences likewise has little or nothing to do with analyzing the survey data at issue. Parroting the survey conclusions

without offering further analysis, and acknowledging that even the “opinions” that she offers unique to her reports (generic pricing) are “outside the scope of [her] quantitative surveys,” she offers no actual relevant independent opinions. Thus Curtis's opinions fail the “fit” test of the Daubert standards for expert testimony.

(States’ Mot. 20–21.)

The States’ argument appears to misunderstand the subject of the “fit” inquiry. As noted above, the issue of fit “is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.” In re TMI Litig., 183 F.3d 613, 670 (3d Cir. 1999). To determine whether an expert's testimony “fits” the proceedings, this Court asks whether it “will help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a); see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 (3d Cir. 2020).

*20 Dr. Curtis's testimony “fits” these proceedings. The States contend that a substantial portion of film prescriptions resulted from Defendant's false marketing/safety campaign. Dr. Curtis attempts to rebut this theory by opining that physicians and patients chose film for reasons other than safety. Thus, Dr. Curtis's opinions do, in fact, relate to an issue in this case.

For all of the reasons noted above, the States’ Daubert Motion will be denied.

V. DEFENDANT'S OMNIBUS MOTION TO PRECLUDE EXPERTS

The next Daubert motion before me is Defendant's Omnibus Motion to Preclude certain of the opinions of the DPPs’ experts Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot. Given the large range of expert opinions challenged, I address each expert individually.

A. Certain Opinions of Dr. Nicholas Jewell

Defendant first challenges certain portions of the opinions offered by the DPPs’ expert Nicholas Jewell. (Def.’ Omnibus Daubert Motion (“Def.’s Omnibus Mot.”), Ex. 17, Report of Nicholas Jewell (“Jewell Rep.”).) According to Defendant, there is extensive evidence, particularly in the form of two “RADARS studies,”¹⁰ indicating that film is less likely than tablets to result in pediatric exposures, or in abuse, misuse, or diversion. Dr. Jewell has been offered by the DPPs to rebut this evidence and opine that neither the available data nor the scientific publications interpreting this data provide a meaningful way to compare film and tablets. Defendant seeks to exclude two aspects of Dr. Jewell's opinions: (1) any efforts to compare film and tablets; and (2) opinions on the subjective states of mind of Defendant's expert witnesses and other scientists.

1. Comparisons Between Film and Tablets

At his deposition, Dr. Jewell was asked, “am I correct that you did not make any affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric?” to which he replied, “That was not part of my charge, and I don't have access to the information to complete that.” (Def.’s Omnibus Mot., Ex. 22, Dep. of Nicholas Jewell (“Jewell Dep.”) 24:24–25:6.) He also testified that he “was not asked to quantify or determine...the relative safety of any product” and did not make a determination, one way or the other, as to whether Film is more, less, or equally likely to result in pediatric exposures, as compared to tablet products.” (Id. at 22:21–23:9.) Based on this testimony, Defendant now seeks to preclude Dr. Jewell from testifying that film is no safer than tablet products under any metric including pediatric exposures, abuse, and diversion. It also seeks to exclude any opinion from him that film is inferior in any respect to tablet products.

Dr. Jewell's expert report, however, does not attempt to opine that film is no safer than or inferior to tablet products. Rather, his report seeks only to identify flaws regarding the accuracy and reliability of the RADARs surveys upon which Defendant's experts rely to opine that film is safer. He summarizes his opinions, in pertinent part, as follows:

*21 10. It is a basic axiom in the field of statistics that the conclusions that can be drawn from a statistical study or analysis are only as reliable as the data from which those conclusions are drawn. Here, as detailed below, the conclusions set forth in the RADARS I and RADARS II articles—including that [Suboxone](#) film formulation was ‘safer’ than the tablet formulation because the film ‘caused’ lower rates of adverse events than tablets—were unreliable from a statistical perspective because the conclusions were based on data that was of poor quality. The data do *not* allow accurate quantification of claimed safety improvements, nor reliable statistical inference regarding whether observed differences in adverse event rates are due to chance or other factors, as opposed to the formulation used or its packaging. As a result, no reliable conclusions could be drawn from the analyses in the articles, especially concerning an issue as complex and multi-faceted as causation....

11. The conclusions in the RADARS articles were also unreliable because the analyses upon which they were based were not designed to draw reliable conclusions about issues such as causation—i.e., whether any observed differences in adverse events between the two formulations were due to, or caused by, differences in the two formulations, such as their packaging, or were due to chance or myriad other potential *confounding* factors. Even if we were to presume that the data used in the RADARS articles were reliable, the RADARS articles could do nothing more than generate a hypothesis about whether the film formulation caused a decline in adverse events....Since no...robust studies were performed, no reliable statistical conclusions could be drawn in this case.

12. Similarly, the RADARS I and II articles both fail to establish the “root causes” of any claimed differences in the prevalence or rates of adverse events between the film and tablet formulations. In other words, the articles proving nothing about *what caused* such differences, and specifically whether such differences (if they existed) were due to the formulation used (film or tablet)....

(Jewell Rep. ¶¶ 10–12 (emphasis in original) (footnotes omitted).)

Dr. Jewell does not offer any independent scientific comparison of film and tablets. Instead, he relies on his statistical expertise to review and identify defects in the studies relied upon by Defendant's experts. In turn, he concludes that any opinions reached by Defendant's experts as to film's alleged superiority in terms of safety are not entitled to any weight. Such testimony is admissible. See [Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc.](#), 546 F. Supp. 2d 155, 168 (D.N.J. 2008) (admitting expert who was proffered to identify methodological flaws in defendants’ audit).

2. Subjective States of Mind of Defendant's Witnesses

Defendant also seeks to exclude Dr. Jewell's reports to the extent they seek to opine on the states of mind of Defendant's expert witnesses and other scientists. Specifically, in his report, Dr. Jewell opines that the RADARS studies suffer from a lack of independence from Defendant. (Jewell Rep. ¶ 40.) Dr. Jewell explains that:

13. [T]here was a distinct lack of independence between the scientific investigators who conducted the RADARS analyses and the research sponsors [Reckitt]. Indeed, the RADARS organization, in addition to receiving a \$75,000 from [Reckitt] for the RADARS I manuscript, received a subscription fee of \$650,000 from [Reckitt] for access to data (and hourly rates for any additional services). In addition, Venebio, [Reckitt's] paid consultant, worked closely with RADARS on the articles. These financial interrelationships—and the fact that [Reckitt] put substantial pressure on RADARS to complete work product by tight deadlines in order to achieve [Reckitt's] business objectives—call into question the reliability and objectivity of any conclusions reported in the RADARS articles.

14. Additionally, I have considered certain analyses that [Reckitt] funded, or performed, concerning comparative persistence and compliance rates between users of [Suboxone](#) film and [Suboxone](#) tablets. These analyses are also problematic in establishing any clear benefit of the [Suboxone](#) film formulation over tablets. Comparative data on persistence and compliance based on various forms of pharmacy and insurance claims data are insufficient to assess these concepts reliably, particularly

in the absence of adjustment for differential patient costs. Even taken at face value, the results were equivocal with regard to any advantage of one [Suboxone](#) formulation over the other.

*22 (Jewell Rep. ¶¶ 13–14.) Dr. Jewell goes on to expand in detail on this alleged bias in the substance of his report. (Id. ¶¶ 40–49, 96; Def.’s Omnibus Mot., Ex. 18, Nicholas Jewell Rebuttal Report (“Jewell Reb. Rep.”) ¶¶ 11–12.) Defendant presses that such opinions must be excluded because lack of objectivity is a matter for the trier of fact to resolve and that expert witnesses who may not testify regarding intent, motive or state of mind.

To some extent, Dr. Jewell’s opinion is properly focused on whether the surveys at issue were based on the “proper safeguards to insure accuracy and reliability.” [Pittsburgh Press Club v. United States](#), 579 F.2d 751, 755–59 (3d Cir. 1978) (noting that a statistically proper survey requires that: “[1] [a] proper universe must be examined and a representative sample must be chosen; [2] the persons conducting the surveys must be experts; [3] the data must be properly gathered and accurately reported; [4] the sample design, the questionnaires and the manner of interviewing [must] meet the standards of objective surveying and statistical techniques; [5] the survey must be conducted independently of the attorneys involved in the litigation; and [6] the interviewers...ideally should be unaware of the purposes of the survey or litigation”) A substantial portion of Dr. Jewell’s report opines that these specific safeguards were not in place in the RADARS I and RADARS II studies. (See, e.g., Jewell Rep. ¶¶ 40 (“although there are substantial limitations of any analysis of passive reporting data, one common advantage is that there is usually no relationship between the reporting system and the investigators analyzing the data. However, this firewall is not present here...”); ¶ 43 (“The relationship between [Reckitt] and Venebio [a separate consulting firm that collaborated with RADARS on Reckitt’s behalf] was not independent in the sense of being at ‘arms-length.’ ”); id. (“In my experience, it is unusual for sponsors to collaborate with researchers in funded academic research in such a way.”). These opinions may be admissible, and Dr. Jewell can explain to the jury, from a statistical perspective, whether Defendant’s involvement in and financing of the study violated these standards of accuracy and reliability.

To the extent, however, that Dr. Jewell seeks to venture beyond such opinions and testify that Defendant’s experts and scientists were impartial or biased, such testimony will be excluded. See [Bracco Diagnostics, Inc. v. Amersham Health, Inc.](#), 627 F. Supp. 2d 384, 440 (D.N.J. 2009) (precluding pharmaceutical expert from testifying as to what pharmaceutical company was “trying” to do with its marketing strategy and what it believed was right or wrong); [Deutsch v. Novartis Pharms. Corp.](#), 768 F. Supp. 2d 420, 433, 443 (E.D.N.Y. 2011) (stating that the expert “walks a fine line between testifying as to what information is reflected in certain documents, and testifying to what certain individuals at Novartis thought about the information and their motivations for characterizing the information in a particular way”). Opinions regarding state of mind or intent are not permissible subjects of expert testimony. See [In re Tylenol \(Acetaminophen\) Mktg., Sales Practices, & Prods. Liab. Litig.](#), 181 F. Supp. 3d 278, 295 n.27 (collecting cases holding that expert witnesses are not permitted to testify regarding intent, motive, or state of mind, or evidence by which such state of mind may be inferred).

*23 Examples of such impermissible opinions are scattered throughout Dr. Jewell’s report. By way of example, he opines that: “part of RADARS’ interest in [Defendant] was presumably to encourage the pharmaceutical company to subscribe to their data resource efforts, thus supplying funds directly to RADARS,” “it appears that [Defendant’s] interest in RADARS I and II extended beyond simple research goals,” and “[Defendant’s] representatives were unhappy with the interim report on the RADARS project that was provided by Venebio on August 31, 2012, in part because of the delayed timing of completion of the final version of a RADARS I manuscript.” (Jewell Rep. ¶¶ 40, 47, 49; see also id. ¶¶ 41, 44, 45, 46.) For the reasons set forth above, I will grant Defendant’s motion to exclude any portion of Dr. Jewell’s testimony that comments on state of mind.

B. Certain Opinions of Dr. Laurence Westreich

The next subject of Defendant’s [Daubert](#) motion is Dr. Laurence Westreich, an associate professor of clinical psychiatry at NY Medical School. Dr. Westreich has peer reviewed more than a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. (Def.’s Omnibus Mot., Ex. 19, Rep. of Laurence Westreich (“Westreich Rep.”) ¶¶ 5–18.) He offers four opinions: (1) Defendant did not have substantial scientific evidence to support its safety claims regarding [Suboxone](#) tablets as compared to film; (2) Defendant’s statements that tablets presented a public

risk because they had higher risks of misuse, abuse, diversion, and pediatric exposure than film would have been important to a reasonable Suboxone prescriber; (3) the expectation that tablets would be withdrawn from the market would have been important to a reasonable Suboxone prescriber; and (4) causing physicians to be suspicious of their patients and/or creating a conflict between physicians' and patients' interests would likely undermine patient treatment and medical outcomes and is therefore inconsistent with Reckitt's statements that it promoted Suboxone film in order to improve the patient experience and public health. (*Id.* ¶ 29.)

Defendant now argues that three portions of Dr. Westreich's report must be excluded. First, Defendant contends that the portion of the report regarding the "RADARS I" article was not prepared by Dr. Westreich and, therefore, he cannot testify as an expert regarding that article. Second, Defendant challenges Dr. Westreich's opinion that Defendant's marketing influenced other physicians. Finally, Defendant asserts that Dr. Westreich's opinions regarding subjective motivations should be excluded.

1. Opinions Regarding the RADARS I Article

Defendant first seeks to exclude the portion of Dr. Westreich's report that challenges the reliability and validity of the RADARS I study. As noted above, this analysis studied the "Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine in Young Children," and was published in the November 2013 volume of *Journal of Pediatrics*. (Westreich Rep. ¶ 122.) RADARS I concluded that "[e]xposure rates to film formulations are significantly less than to tablet formulations." (Def.'s Omnibus Mot., Ex. 27., at 1.) The DPPs rely on this study to support the fact that the switch to film was for procompetitive reasons. Dr. Westreich opines—over the course of sixteen pages and thirty-seven paragraphs—that multiple aspects of the RADARS study were problematic, thus affecting its reliability. (Westreich Rep. ¶¶ 122–58.)

According to Defendant, Dr. Westreich should be precluded from commenting on the RADARS study because he revealed, at his deposition, that he knew almost nothing about the RADARS I article. Specifically, when asked about it, the following exchange occurred:

Q. Dr. Westreich, are you familiar with Exhibit 9 [RADARS I article]

*24 A. I've seen this article, yes.

Q. Can you tell me—well, have you spent any time analyzing this article?

A. I have looked at it, yes.

Q. And have you come to any conclusions about it?

A. I want to make certain I know which article this is here. I've seen this article, but I haven't done a great deal of analysis of it.

Q. Okay. Have you examined—well how much analysis have you done of exhibit 9?

A. Not very much.

(Def.'s Omnibus Mot., Ex. 21, 201:12–202:2.) Defendant points out that during the course of this testimony, Dr. Westreich took multiple pauses and spent extensive amounts of time flipping through both the article and his report. (Def.'s Omnibus Mot., Ex. 86, Video Clip of Westreich Dep.) Indeed, Defendant notes that Dr. Westreich could not answer a simple question about "what data sources are used" in the article without taking additional time to look through the article. (Westreich Dep. 202:3–25.) From this, Defendant surmises that "[g]iven the extraordinary level of detail of [Dr. Westreich's] report [on RADARS I], Dr. Westreich's unfamiliarity with RADARS I at the deposition is utterly inconsistent with the notion that this portion of his report was 'prepared...by the witness' within the meaning of Rule 26(a)(2)(B)." (Def.'s Omnibus Mot. 9.) Defendant asserts that because Dr. Westreich clearly did not author this portion of the report, *Federal Rule of Civil Procedure 26(a)(2)* requires that it be excluded.

In response, the DPPs contend that various copies of the RADARS I article had been produced in varying formats throughout discovery, none of which say “RADARS I” in the title. Therefore, when first shown the article in his deposition, Dr. Westreich initially did not recognize it and needed to refresh his recollection. The parties took a break in the deposition, after which Dr. Westreich made a correction in his testimony, as follows:

A. I failed to identify one of the articles that I did look at in some depth which is the root cause, clinical facts and outcomes of unintentional exposure to buprenorphine in children. In fact, I wrote several pages in my report.

Q. Was the article unfamiliar to you when you saw it in this deposition?

A. Actually, the face of it was because it looked different as I was reading it. There's two Lavonas articles [RADARS I and RADARS II], so it was unfamiliar to me.

Q. Are you less familiar with the other Lavonas article?

A. Am I less familiar with the other one?

Q. Yes.

A. I don't believe so, no.

Q. How did it come to your attention that you had made an error on the record?

A. As you were asking me about it, it seemed very familiar, but since this one looked different, I wasn't able to identify it, and I realized that as we were talking.

Q. When we were off the record, did you have any conversation with anyone about this error in the record. [Objection regarding attorney-client privilege]

(Westreich Dep. 212:10–213:23.) Plaintiff now argues that Dr. Westreich's “brief lapse of recall during deposition,” particularly in the face of his sworn testimony that he recognized the RADARS I study and had discussed it in his report, does not warrant exclusion of this part of his report.

***25** [Federal Rule of Civil Procedure 26](#) requires that expert reports be “prepared and signed by the witness....” [Fed. R. Civ. P. 26\(a\)\(2\)\(B\)](#). Although the Advisory Committee Notes to [Rule 26](#) state that the Rule “does not preclude counsel from providing assistance to experts in preparing the reports,” [Fed. R. Civ. P. 26](#) advisory committee's notes (1993), [Rule 26\(a\)\(2\)\(B\)](#) “does not contemplate blanket adoption of reports prepared by counsel or others....” 6 James Wm. Moore et al., [Moore's Federal Practice](#) ¶ 26.23[4] (3d ed. 2000).

Dr. Westreich's report is 123-pages long and his reference to the RADARS study is extensive. Dr. Westreich's initial confusion certainly does not establish, under [Daubert](#) standards, that he did not prepare that portion of his report.¹¹ Dr. Westreich's deposition reflects that he was originally unclear about the nature of the RADARS I report, but, after having an opportunity to review that report, he was able to quickly and directly answer multiple questions in detail about the study. (Westreich Dep. 202:19–211:17.) Immediately after questioning on that report, counsel took a break in the deposition. When the parties returned from the break, Dr. Westreich corrected his testimony—on the record and under oath—and stated that he had in fact reviewed the study in detail.

As noted by one district court faced with a similar allegation that an expert did not prepare his own report:

Litigation continually proceeds with assumptions that any witness, expert or otherwise, may have made different and sometimes inconsistent statements about relevant matters. The inconsistencies often relate to inconsequential details. They

may also relate, of course, to material matters. Inconsistencies occur for various reasons. Memories dim. People make mistakes in recall. They sometimes speak carelessly, impulsively, and with little thought or discretion about their choice of language. They choose words which inadequately or inaccurately express what they mean to say. Trial courts often instruct juries, in weighing the credibility of witnesses, to consider whether their inconsistent statements relate to matters of material importance or of lesser consequence and whether they reflect either honest mistake on the one hand or an intent to deceive on the other.

*26 The court generally would not disqualify a witness upon grounds he has changed his testimony after talking with an attorney. It would instead give opposing counsel the opportunity to cross-examine the witness. Effective cross-examination serves to expose inconsistencies of importance. It may also develop the extent to which a witness has been influenced by counsel to make changes in what he says. Similarly here. That a report of the expert has been revised, after a conference with the attorney, should not lead the court to hastily strike the designation of the witness. Defendant should instead find his recourse by cross-examination of the expert.

Marek v. Moore, 171 F.R.D. 298, 301–02 (D. Kan. 1997).

At trial, Defendant will be given significant leeway to further probe this issue before the jury and, if justified, re-raise its motion to exclude this portion of Dr. Westreich's testimony.

2. Opinions Regarding Influence of Defendant's Marketing on Physicians

Defendant next seeks to exclude the section of Dr. Westreich's report stating that “Reckitt's Film-superiority statements and withdrawal statements would have been important to the reasonable Suboxone prescriber.” (Westreich Rep. § V.) In this section, Dr. Westreich opines that “[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical associations, and interacting with other doctors,” the “average, reasonable” physician would be impacted and influenced by Reckitt's claims about the tablets’ dangers, would have maintained an anti-tablet bias after generic tablets became available, and would have factored information about impending tablet withdrawal into their treatment decisions. (Id. ¶¶ 235–70.)

Defendant contends that such opinions regarding what other doctors deem material must be based on something more reliable than simply the expert's own experience as a doctor. Defendant asserts that a naked reference to “experience” is not a reliable methodology; rather the expert must explain how that experience leads to the conclusion reached. According to Defendant, Dr. Westreich's report never explains how his experience leads to his conclusions and, as such, any statement as to what other physicians with certain information would think is purely speculative and not based on scientific knowledge.

The DPPs respond that Dr. Westreich's opinions are appropriately based on his decades of experience training medical students to treat addicted patients, as a psychiatrist making treatment decisions for patients, and as a peer reviewer of scholarly articles. The DPPs point out that Dr. Westreich also reviewed sufficient evidence, including Reckitt field reports and internal analyses about how doctors in fact reacted to the promotional statements, including a December 2010 Reckitt survey of 300 doctors about why physicians prefer Suboxone film over tablet.

Where traditional Daubert reliability factors are not workable, the Supreme Court has noted that the “relevant reliability inquiry concerns may focus upon personal knowledge or experience.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). Indeed, expert testimony may be based on “experience alone—or experience in conjunction with other knowledge, skill, training or education.” Fed. R. Evid. 702, advisory committee's note 2000. “In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” Id.; see Kumho Tire Co., 526 U.S. at 156, 119 S.Ct. 1167 (“[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”).

With respect to the particular testimony at issue here, the Third Circuit has recognized that a doctor's experience alone renders him a reliable witness to testify about a reasonable standard of care or what a reasonable physician would do. [Schneider ex rel. Estate of Schneider v. Fried](#), 320 F.3d 396, 405–07 (3d Cir. 2003) (reversing exclusion of expert testimony about standard of care during pre-treatment for angioplasty). Consistent with that principle, numerous cases have held that a doctor may, based on his or her experience, “testify about what a reasonable doctor *should* know” or “how a reasonable doctor would interpret [a] safety warning.” [Bartlett v. Mut. Pharm. Co., Inc.](#), 742 F. Supp. 2d 182, 196 (D.N.H. 2010) (emphasis in original); see also [In re Bard IVC Filters Prods. Liab. Litig.](#), No. MDL 15-2641, 2018 WL 495188, at *4 (D. Ariz. Jan. 22, 2018) (“The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his opinion as to the information reasonable physicians expect to receive from IVC manufacturers, and whether physicians who implant IVC filters reasonably expect a properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring organs.”); [Deutsch v. Novartis Pharms. Corp.](#), 768 F. Supp. 2d 420, 440, 443 (E.D.N.Y. 2011) (finding that doctor could opine, based on professional experience alone, whether warning labels on drug were false or misleading from the perspective of a reasonable prescribing physician and whether certain information contained in drug company's internal documents regarding risks of drugs would have been useful to doctors in making prescribing decisions).

*27 However, “most courts have prohibited experts from testifying ‘about what all doctors generally consider in making prescription decisions’ or about ‘what doctors generally think,’ unless the testimony is based on something more reliable than simply the expert's own experience as a doctor.” [Bartlett](#), 742 F. Supp. 2d at 196 (quoting [In re Diet Drugs Prods. Liab. Litig.](#), No. MDL 1203, 2000 WL 876900, at *11–12 (June 20, 2000)) (additional citations omitted); see also [In re Loestrin 24 Fe Antitrust Litig.](#), 433 F. Supp. 3d 274, 302–03 (D.R.I. 2019) (holding that doctor may not testify as to what all physicians do or consider in making prescribing decisions, but may testify as to his own prescribing decision-making process and knowledge, as well as that of his colleagues or other doctors with whom he has personal experience); [In re Rezulin Prods. Liab. Litig.](#), 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (“Unlike opining about what physicians in general expect to see on a label, [expert]’s surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge.”); [In re Seroquel Prods. Liab. Litig.](#), No. MDL 06-1769, 2009 WL 3806436, at *8 (M.D. Fla. July 20, 2009) (holding that expert doctors may express opinions regarding accuracy and adequacy of drug label without reference “to the asserted perceptions of other doctors” or whether doctors generally understand the contents of the label).

Here, Dr. Westreich's report tiptoes the line between properly opining how Defendant's marketing materials affected both his prescribing decisions and those of physicians with which he has had contact, and improperly speculating what impact those marketing materials had on the prescribing decisions of all physicians. To clarify where that line follows, I hold that Dr. Westreich may testify that Reckitt's statements regarding safety risks of tablets versus film would be material to him and, in his experience, the reasonable Suboxone prescriber. He may not, however, testify that “when Reckitt Benckiser representatives reported that Suboxone Tablets were prone to inadvertent pediatric exposure, misuse, and diversion, doctors would of course assume that the generic buprenorphine/naloxone tablets would have the exact same set of side effects and adverse effects” and would “remain reluctant to prescribe buprenorphine/naloxone tablets of any sort.” (Westreich Rep. ¶ 255.) Similarly, while he may opine about why he would not prescribe a medication that would soon be withdrawn from the market, he cannot opine that “[i]f a particular medication or preparation will soon be withdrawn from the market, most doctors would stop prescribing that medication[] to new patients and would start transferring their patients to other medications or preparations.”¹² (*Id.* ¶ 268.) Thus, to the extent Dr. Westreich limits his testimony to what factors he considers in making prescribing decisions, it will be admissible.¹³ To the extent he seeks to speculate what other physicians generally did or would do, such testimony will be excluded.

3. Opinions Regarding Subjective Motivations

*28 Defendant's final challenge to Dr. Westreich alleges that his opinions regarding subjective motivations should be excluded. Specifically, like Dr. Jewell, Dr. Westreich opines that researchers were biased due to their interactions with Reckitt. (Westreich Rep. ¶¶ 144–58, 189–92, 232.) Dr. Westreich also opines that Defendant's expert, Dr. Murrelle, “has a self-interest and

motivation to not find any flaws with reports that his company [Venebio]...aided Reckitt in developing.” (Def.’s Omnibus Mot., Ex. 20, Westreich Rebuttal Report (“Westreich Reb. Rep.”) ¶ 32.)

As noted above, Dr. Westreich has peer reviewed more than a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. Thus, like Dr. Jewell, Dr. Westreich may permissibly testify, based on his experience in peer review, regarding whether the circumstances under which reports or other studies were prepared violated well-established safeguards on independent, accurate, and reliable studies.¹⁴

But Dr. Westreich also ventures into the impermissible territory of commenting on state of mind. By way of example, he states:

- “The documents indicate to me that Reckitt made clear to Venebio that Reckitt was ‘the customer’ and that the project’s methodology and design should be tailored to Reckitt’s specific ‘business goals.’ ” (Id. ¶ 148.)
- “Furthermore, the documents indicate that, from the outset, the parties understood that Venebio would allow Reckitt to influence the paper’s wording.” (Id. ¶ 150.)
- “In my opinion, Reckitt’s involvement in setting the project objectives, designing and implementing the protocols, and drafting the manuscript calls into question Venebio’s statement in the published paper that ‘The authors had full control of all aspects of study design, data collection, data analysis and management, and the decision to publish. Reckitt Benckiser Pharmaceuticals was able to review the manuscript only for proprietary information.’ ” (Id. ¶ 154.)
- “In my opinion, the references to ‘getting the budgeting secured’ and ‘business usefulness’ telegraph Reckitt Benckiser’s desire to get results which would advance its business interests, or it would not fund the project.” (Id. ¶ 191.)
- “Dr. Murrelle’s bias in assessing his own studies also cannot be ignored. Since he is employed by the very entity whose research he is defending, and he produced the research himself, bias in favor of that research is inevitable. He has a self-interest and motivation to not find any flaws with reports that his company, Venebio, aided Reckitt in developing.” (Westreich Reb. Rep. ¶ 32.)

Similar to my finding regarding Dr. Jewell, Dr. Westreich may not comment on state of mind or the credibility of Defendant’s researchers and expert witnesses. See [In re Seroquel](#), 2009 WL 3806436, at *8 (“[I]t is one thing for an expert to testify...to explain and compare information in Seroquel marketing materials to other evidence—and quite another matter for an expert witness to render an opinion concerning what a drug company intended or sought to achieve through the use of those marketing materials. The latter are proper subjects for closing argument, not expert testimony.”). Accordingly, I will grant Defendant’s motion to exclude any portion of Dr. Westreich’s testimony that comments on subjective motivations.

C. Certain Opinions of Yvonne Tso

*29 The DPPs have identified Yvonne Tso as an expert in managed care with different types of healthcare and healthcare-related experiences acquired over the course of thirty years. (Def.’s Omnibus Mot., Ex. 14, Report of Yvonne Tso (“Tso Rep.”) ¶ 1.) Ms. Tso offers several opinions:

1. Reckitt’s tablet withdrawal statements, public health risk statements, and pricing tactics would have been relevant to the typical, reasonable Managed Care Organization (“MCO”) decisionmaker’s decisions regarding film and tablet placement and likely resulted in decisions that gave film favorable formulary placement and blocked or restricted coverage for [Suboxone](#) tablets;
2. Reckitt’s statements about tablet’s higher risks of misuse, abuse, diversion, and pediatric exposure would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the purportedly less safe product (tablets) and favor the utilization of the purportedly safer product (film);

3. Reckitt's pattern of raising tablet prices during the pre-generic period, combined with eliminating tablet rebates, would place enormous economic pressure on the typical, reasonable MCO decisionmaker to make formulary adjustments to drive patients and doctors to film;
4. Reckitt's combined tactics from 2009 through 2012 would have been significant and material to a typical, reasonable MCO decisionmaker's formulary decisions to favor film and disfavor tablets, which in turn made tablets economically inaccessible to patients and imposed costly administrative burdens on doctors who prescribed tablets; and
5. Reckitt's conduct had the effect of entrenching film in the market, making it difficult for many MCOs to disfavor film on formularies after generic tablets entered.

(Tso Rep. ¶¶ 17–23.)

Defendant raises two challenges to Ms. Tso's opinions. First, it contends that Ms. Tso's bald invocation of her “experience” is not a basis for her opinions and, absent any testimony of her actual experiences, her methodology is unreliable. Second, it asserts that Ms. Tso ignored contrary evidence, thus rendering her opinions impermissibly speculative.

1. Invocation of “Experience” as Methodology

Defendant first challenges Ms. Tso's opinions about the materiality and causal effect of Defendant's alleged withdrawal and safety statements because such opinions are based solely on her “experience.” According to Defendant, Ms. Tso did not conduct any type of survey to ascertain the impact of the communications at issue and has never asked anyone at a managed care organization (“MCO”), health plan, or pharmacy benefit manager (“PBM”) about how they reacted to the alleged statements at issue. Defendants note that, at her deposition, Ms. Tso did not explain how her experience led to the conclusion reached, could not recall any of her actual experiences in determining formulary placements or other directly applicable experiences, could not remember examples of any analogous situations, and testified contrary to her own experience regarding safety claims.

While these alleged deficiencies may provide useful cross-examination, this challenge is an insufficient basis on which to exclude Ms. Tso's testimony. “The text of [Rule 702](#) expressly contemplates that an expert may be qualified on the basis of experience. “In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” [Fed. R. Evid. 702](#), Advisory Committee's Note (2000). “If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.” *Id.* Repeatedly, courts have permitted experts to rely solely on their experience to opine on how a reasonable individual within the same industry would react. *See, e.g., In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, MDL 09-2100, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) (“As the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Dr. Kessler may testify about what a reasonable FDA official would have done with information about VTE adverse events.”); [Krommenhock v. Post Foods, LLC](#), 334 F.R.D. 552, 579 (N.D. Cal. 2020) (declining to exclude advertising expert opining, based on experience alone, about the impact that advertising has on consumer perceptions regarding the health and wellness benefits of consumer products generally and consumer behavior and decision-making as it relates to labeling claims on cereal packaging, even though expert did not conduct a focus groups or consumer testing); [Veleron Holding, B.V. v. Morgan Stanley](#), 117 F. Supp. 3d 404, 445 (S.D.N.Y. 2015) (expert on banking industry standards “had worked in five of the preeminent firms in a highly competitive industry” and had “become acquainted with each firm's code of conduct during his years of service,” so “the fact that he did not conduct a ‘survey’ before reaching his conclusion, or did not obtain a copy of every other bank's internal policies, is at best an avenue for cross-examination, rather than a disqualification from testifying.”).

***30** I find that Ms. Tso's testimony is permissible given the complex nature of formulary decisions by managed health care organizations. Ms. Tso may offer such opinions based on her experience as a retail and hospital pharmacist, in

healthcare financing, and within managed care organizations where she was involved with all aspects of pharmaceutical benefit administration, formulary, and utilization decisions. (Tso Rep. ¶¶ 1–10.) Although she did not conduct any particular surveys, her experience alone qualifies her to opine on how Defendant's safety messages, tablet withdrawal statements, and practice of raising tablet prices would have factored into a reasonable, objective MCO decisionmaker's formulary adjustments. Ms. Tso also bolstered her opinion by citing to documentary and testimonial evidence that MCOs in fact made formulary decisions because of Defendant's withdrawal statements and claims that film was safer, and she explained the precise reasons how and why Defendant's actions impacted formulary and prescribing decisions. (Tso Rep. ¶¶ 38, 42, 53, 72, 74, 104, 115, 138, 150–51.)

Regarding Defendant's challenges to Ms. Tso's inability during her deposition to testify (a) about her actual experiences in determining formulary placement for these particular products, (b) in understanding what withdrawal or safety concerns were raised in her presence, or (c) even to identify examples of analogous situations, these are insufficient reasons for exclusion. Ms. Tso was able to identify several companies for she was involved in a formulary decision involving buprenorphine products. (Def.'s Omnibus Mot, Ex. 54, Dep. of Yvonne Tso ("Tso Dep.") 46:10–47:7.) She went on to state that "I don't think I can name all of them *because there are so many*." (*Id.* at 47:12–13 (emphasis added).) Although Defendant asserts that Ms. Tso had no recollection of her actual experiences in determining formulary placement for these products, my reading of her testimony differs. She explained that her experience with respect to buprenorphine drugs was so vast and varied, much of it occurring years earlier, she simply could not recall the particulars for each of the discussions. (*Id.* at 49:7–56:24.) Any memory lapses as to specific conversations in years past are simply a basis for cross-examination.

I also find no merit to Defendant's allegation that Ms. Tso's opinion on the safety claims is belied by her testimony about her actual experiences. As noted above, Ms. Tso opined that Defendant's safety statements about the tablet would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the tablet. At her deposition, however, Ms. Tso testified that MCOs retain Pharmacy and Therapeutics committees to evaluate marketing claims by pharmaceutical companies and determine if they are corroborated by scientific studies. (Tso Dep. 72:3–73:9.) While such testimony perhaps affects the weight of her opinion, it does not, under Daubert standards affect its reliability.

2. Failure to Consider Contrary Evidence

Defendant's second challenge to Ms. Tso's testimony contends that she simply ignored contrary evidence regarding both alleged tablet-withdrawal and safety-claim statements. With respect to Defendant's alleged tablet-withdrawal communications, Defendant alleges that Ms. Tso failed to identify a single instance where a "withdrawal statement" caused any MCO to remove Suboxone tablets from a formulary. With respect to Defendant's alleged safety claims regarding tablets, Defendant argues that Ms. Tso (a) failed to explain why these communications did not deter commercial insurers from near-universal coverage of generic tablets, and (b) could only identify one MCO as having made a formulary decision based even in part on safety considerations.

Defendant's argument "reflects a fundamental confusion about the role of the court as a gatekeeper, under Daubert, to determine the admissibility of evidence, and the role of the jury, as a fact finder, to determine the weight to be accorded to admitted evidence." ID Security Canada, Inc. v. Checkpoint Systems, Inc., 249 F. Supp. 2d 622, 691–93 (E.D. Pa. 2003). As has become a mantra throughout this opinion, the Supreme Court has admonished that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); see also In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 427 (S.D.N.Y. 2016) ("To whatever extent Defendants' public or internal statements conflict with its experts' opinions or its litigation positions in these cases, that will be a problem for Defendants that Plaintiffs may exploit via cross-examination and argument. But Defendants' experts' failure to confront alleged conflicting statements ... does not warrant exclusion under Daubert.").

*31 As Ms. Tso's failure to address potential factual inconsistencies does not bear on the reliability of her testimony and may be tested through cross-examination, I will deny Defendant's Daubert motion on this ground.

D. Certain Opinions of Robert Verscharen

Defendant's omnibus Daubert Motion next challenges identified DPP expert Robert Verscharen. Mr. Verscharen—an individual with forty years' experience in the pharmaceutical industry—was retained by the DPPs as an expert on the business of pharmacy purchasing and dispensing of prescription drugs at the retail level. (Def.'s Omnibus Mot., Ex. 15, Robert Verscharen Report ("Verscharen Rep.") ¶ 1.) His report (1) describes the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution; (2) opines that the AB-rating is the linchpin of the savings to drug purchasers at all levels of the distribution chain; and (3) explains that therapeutic substitution is not as efficient or effective as AB-rated substitution in delivering cost savings to purchasers, dispensers and consumers, and why a therapeutic substitution program to move prescriptions from Suboxone film to generic tablets, if it had been attempted, would have been inefficient and unsuccessful.¹⁵ (Id. ¶ 9.)

Defendants move to preclude these opinions on two grounds. First, to the extent that Mr. Verscharen claims that competition between film and generic tablets was hindered at the pharmacy counter due to the lack of automatic substitution, Defendant contends that the DPPs withheld evidence on this subject during discovery and may not now proffer an expert on this subject. Second, Defendant posits that Mr. Verscharen's opinion that "therapeutic substitution programs in general are difficult, inefficient, and rarely successful" lacks both an adequate basis and a reliable methodology.

1. Exclusion Based on Failure to Produce Evidence

Defendant first maintains that, during discovery, it requested that DPP class representative Meijer, Inc.—which runs a chain of pharmacies—produce "[a]ll documents relating to the switching between or among Buprenorphine Products" and documents relating to sales and communications regarding sales of these products. (ECF No. 178-1, Req. Nos. 2, 12, 14.) Presumably, Defendant requested this discovery because it bore on whether there was any antitrust impact resulting from Defendant's alleged actions. Meijer objected to such production, arguing that although documents relating to its purchases were relevant, "downstream discovery" relating to sales or interactions with consumers was irrelevant. In response to Defendant's motion to compel documents, Meijer produced a spreadsheet of invoice-level sales data going back seven years, including the date the prescription was filled, a description of the product dispensed, the manufacturer, the dispensed product identifying information, the co-pay information, the insurer or third-party payment information, any dispensing fee collected, any coupon used, the insurer or other carrier used, and an individual patient ID number to track any drug changes or changes in insurance over time. In response to further motion practice regarding this discovery, I found that Meijer's spreadsheet production satisfied their burden. (ECF No. 286-1). When Defendant sought additional information about downstream competition through a Rule 30(b)(6) notice issued to Meijer, Meijer refused to produce a witness on this subject. Defendant now speculates that "[i]t is highly likely that Meijer had responsive documents, as even Mr. Verscharen admits that pharmacies take vigorous efforts to inform consumers of the availability of generic products." It contends that the DPPs cannot offer an expert on a subject regarding which it withheld documents and testimony. (Def.'s Omnibus Mot. 22.)

*32 Reviewing the document requests referenced by Defendant, I see no request directed specifically towards therapeutic substitution and whether it was effective in the absence of automatic substitution between AB-rated products. Moreover, it is not clear that Meijer had any such responsive documents. Indeed, Meijer's own Rule 30(b)(6) witness testified that Meijer had no policies directing substitution of a cheaper generic if the products were not AB rated:

Q. When a pharmacist is presented with a prescription, what should he do according to Meijer's policies?

A. Fill the prescriptions written.

Q. If the prescription is written using the brand name of a drug for which there are substitutes available, what does Meijer's policy direct the pharmacist to do?

...

A. ...If a generic is available, then it would be our pharmacists, within their rights to substitute a generic alternative to help save the patient money.

Q. Does Meijer have a policy regarding whether the pharmacist should do that?

A. No.

Q. Is the goal of Meijer's substitution to save the customer money?

A. Ultimately we are acting on the customer's behalf, and saving them money is very important, yes.

Q. So if a generic substitute is not cheaper, does Meijer have a policy whether or not the pharmacist should substitute in that circumstance?

A. No.

(Meijer 30(b)(6) Dep. 21:25–23:13.) Given such testimony, it is not clear what additional documents Meijer could have produced that Defendant would have used to rebut Mr. Verscharen's opinion that pharmacists can steer patients towards generic products.

As Defendant has not proven that DPPs failed to produce evidence bearing on the substance of Mr. Verscharen's report, I decline to grant Defendant's Motion on this ground. Should Mr. Verscharen testify at trial on subject areas which Defendant believes were the subject of valid but unresponded-to discovery requests, Defendant may raise a relevant objection at that time.

2. Opinions on the Difficult Nature of Therapeutic Substitution Programs

Defendant also objects on the grounds of qualification and reliability with respect to Mr. Verscharen's opinion that “[t]herapeutic substitution programs in general are difficult, inefficient, and rarely successful.” (Verscharen Rep. § B.) Mr. Verscharen asserts that therapeutic substitution seldom occurs because of “the economics of pharmacy,” which considers the difficulties and costs inherent in therapeutic substitution. Specifically, for therapeutic substitution to occur, the patient must be asked if they want the lower-cost generic, the pharmacist has to check insurance coverage, the pharmacist has to discuss costs and benefits with the patient, the physician must be contacted about the substitution and will often not be reached immediately, the pharmacist must document the revised prescription, and ultimately the new prescription must be transmitted to the store. (*Id.* ¶¶ 50–52.) Mr. Verscharen concludes that “the cost to the pharmacy of filling a prescription through a therapeutic substitution, under the best of circumstances (a centralized facility for such functions), is over \$8.00 prescription. This compares with no additional cost for filling a prescription through AB-rated substitution.” (*Id.* ¶ 56.)

While such testimony in itself is admissible, the problem arises with Mr. Verscharen's subsequent opinion that a therapeutic substitution program to move prescriptions from **Suboxone** film to generic **Suboxone** tablets, if it had been attempted, would have been inefficient and unsuccessful. This is because his methodology in reaching this opinion relies on a single example of problems inherent in the therapeutic substitution program relating to the drug **TriCor**. He explains that, in 1998, Abbott Laboratories entered the market with the drug **TriCor** in capsule form, which did not have patent protection. (*Id.* ¶ 59.) In anticipation of threatened generic competition, Abbott developed a tablet form of **Tricor** which would be bioequivalent to, but not AB-rated with, the prior form, and it stopped selling its **Tricor** capsules. (*Id.* ¶ 60.) Thus, by the time generic competitor Teva obtained FDA approval for its generic capsules, the majority of **Tricor** prescriptions were for the tablets. (*Id.*) Because the capsules were not AB-rated to the tablets, Teva could not get automatic substitution at the pharmacy counter. (*Id.* ¶ 61.)

Therefore, Teva decided to launch its capsule product as a branded generic drug, under the name [Lofibra](#), and designed a therapeutic substitution program that encouraged pharmacies to contact physicians and convince them to change their [Tricor](#) prescriptions to the chemical name (fenofibrate) and in the capsule form. (*Id.* ¶ 62.) Teva paid for the program, but ended up cancelling it in less than six months because of a lack of pharmacy participation and/or conversions. (*Id.*) In addition, Teva faced competition from other generic companies who developed generic capsules that were AB-rated to the [Lofibra](#) tablets. (*Id.* ¶ 63.)

*33 From this scenario, Mr. Verscharen opines that [Suboxone](#) presented similar problems with regards to the potential success of a therapeutic substitution program. (*Id.* ¶ 65.) He notes that tablets were not AB-rated to [Suboxone](#) film, so a therapeutic substitution program seeking to switch [Suboxone](#) film prescriptions to generic tablets “was likely to fail,” just as the program seeking to switch [Tricor](#) tablet prescriptions to capsules failed. (*Id.*) He explains that therapeutic substitution of generic tablets for [Suboxone](#) film would have been particularly difficult if, as Plaintiffs allege, there was a three-plus year campaign by Defendant to aggressively disparage the safety of tablets. (*Id.* ¶ 69.) Mr. Verscharen goes on to assert that “even in the unlikely event that a therapeutic substitution program involving [Suboxone](#) was attempted, it is a virtual certainty that the program would result in far less savings to purchasers (including patients) than automatic AB-rated generics would have produced if Defendants had not engaged in the challenged scheme.” (*Id.* ¶ 70.) Finally, he opines that if therapeutic substitution were to become the norm in the pharmaceutical industry, it would result in lower generic substitution and higher prices to consumers because of the cost to the pharmacy of engaging in the therapeutic substitution process.

I do not find that Mr. Verscharen's methodology fits the facts of this case. As set forth above, to determine whether an expert's testimony “fits” the proceedings, this Court asks whether it “will help the trier of fact to understand the evidence or to determine a fact in issue.” [Fed. R. Evid. 702\(a\)](#). Had Mr. Verscharen applied his experience in the pharmaceutical industry to the particular facts here—*i.e.*, whether a generic manufacturer of buprenorphine [naloxone](#) tablets could have successfully launched a therapeutic substitution program for prescriptions written for branded film—his opinion may have helped the trier of fact. However, Mr. Verscharen premised his opinion on only general pharmaceutical experience and a single example from more than a decade earlier when a different generic company's effort to launch a therapeutic substitution for a different drug under different circumstances was unsuccessful. Such an example, while perhaps identifying pitfalls and obstacles in that program, does not easily translate to the same pitfalls and obstacles in a therapeutic substitution program here. Mr. Verscharen had no idea of what Plaintiff Meijer did to switch prescriptions between film and generic buprenorphine [naloxone](#) tablets and made no effort to understand Meijer's opinions and experience. (Def.'s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen (“Verscharen Dep.”) 113:2–23.) He also did not (a) address whether generic manufacturers thought that pharmacies could effectively help switch prescriptions to generics, (b) review any documents from the record regarding how generic manufacturers understood the competition between their products and the film product, or (c) look to see whether the generic manufacturers here tried to advertise their products. (*Id.* at 116:20–117:11.) Finally, Mr. Verscharen admitted that he had done no analysis of how branded [Suboxone](#) film compared to generic buprenorphine [naloxone](#) tablets with regard to any measure of price or profitability and could not say whether patients would typically pay more for film as compared to generic tablets. (*Id.* at 109:6–111:14, 126:6–130:7.) Indeed, at no point did Mr. Verscharen evaluate whether a medicine designed to combat opioid addiction would be suitable for a therapeutic substitution program. (*Id.* at 115:12–18.)

Moreover, even if Mr. Verscharen's testimony could satisfy the “fit” element of [Daubert](#), I cannot find that his methodology on this issue is sufficiently reliable. For witnesses relying solely or primarily on experience, as Mr. Verscharen does here, “then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for an opinion, and how that experience is reliably applied to the facts.” [Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc.](#), 546 F. Supp. 2d 155, 165 (D.N.J. 2008) (citing [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), 43 F.3d 1311, 1319 (9th Cir. 1995)). Mr. Verscharen, however, fails to connect his experience to his opinion. In fact, in his deposition, Mr. Verscharen revealed that his *actual* experiences belie his opinion that a therapeutic substitution for buprenorphine [naloxone](#) products would not work. He testified that he developed and worked in a Therapeutic Intervention Center for Thrift Drug, which was a department consisting of technicians and pharmacists that contact patients and physicians about programs or about products that they feel the physician and the patient should be aware of, and was designed to ensure that pharmacy stores were not taking the time “in doing some of the things that I wanted to communicate to physicians and patients.” (Def.'s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen

(“Verscharen Dep.”) 89:6–24.) More specifically, in lieu of an individual pharmacist engaging in the therapeutic substitution process described above, the center was staffed with approximately thirty technicians who would contact patients about potential cost savings in using a biosimilar drug and, if the patient approved it, the technicians would call the physician and get him/her to change the prescription. (*Id.* at 131:8–133:9.) This Therapeutic Intervention Center actually eliminated the precise time and cost factors at the store level that made the Tricor therapeutic substitution unworkable—factors which Mr. Verscharen now opines claims would make therapeutic substitution unworkable here.

*34 In short, Mr. Verscharen's opinion is not an expert opinion, but rather a personal opinion based on one experience with a generic company trying a similar therapeutic program. He made no effort to specifically apply the factors at issue in that program to the unique circumstances of this case. Accordingly, I find that Mr. Verscharen can testify about the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution. (Verscharen Rep. ¶¶ 16–44.) He can also discuss the efficacy of automatic AB-rated generic substitution and the hurdles he specifically experienced in therapeutic substitution programs. (*Id.* ¶¶ 45–64.) He may not, however, make the speculative leap—as he does in his report—that similar problems would have likely rendered unsuccessful a therapeutic substitution program regarding [Suboxone](#). Accordingly, I will grant this portion of Defendant's Motion.

E. Opinions By Patricia Zettler

Defendant moves to exclude the report of Professor Patricia Zettler, who opines that: (1) Defendant's involvement with the development of shared REMS with the generics directly delayed approval of that shared REMS; (2) had Defendant informed the FDA and the generics on January 12, 2012 that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted BTOD SSRS, six months earlier than actual approval was obtained; (3) Defendant's promotion of the [Suboxone](#) film as less prone to misuse, diversion, and pediatric exposure than the [Suboxone](#) tablet was false or misleading in violation of the Food, Drug & Cosmetic Act's (“FDCA”) and FDA's regulations because the claims were not supported by statistically significant data at the time; and (4) if she were an attorney counseling a drug sponsor client in the position of Defendant, she would have advised her client not to make such safety claims.

Defendant challenges Professor Zettler's first and second opinions on two grounds.¹⁶ First, Defendant argues that Professor Zettler has no expertise regarding how long it takes to assemble an approvable REMS submission, nor does she report any expertise that would inform the assumptions underlying her timeline. Second, Defendant contends that Professor Zettler provides no methodology beyond “wishful thinking.”

1. Qualification

Professor Zettler graduated law school in 2009 and then worked in the Office of the Chief Counsel at the FDA for just under four years, after which she became a law school professor. Given that background, Defendant contends that her practical experience is limited. Citing to her deposition, Defendant notes that Professor Zettler has never advised a pharmaceutical manufacturer or client on proposed promotional messaging, never advised a pharmaceutical manufacturer or client regarding issues pertaining to a shared REMS program, and never served as an expert witness before. (Def.'s Omnibus Mot., Exs. 23–24, Dep. of Patricia Zettler (“Zettler Dep.”) 212:20–213:24.) Defendant also points out that Professor Zettler was never involved in any decision to grant a waiver from a shared REMS requirement and never worked on any shared REMS programs in which a waiver was requested. (*Id.* at 72:13–73:12.) Finally, although she reviewed and commented on REMS for the FDA, Defendant notes that she never drafted any REMS documents for the FDA and could not recall instances of dealing with a schedule by which manufacturers had to put together REMS documentation, (*Id.* at 288:10–294:10.) Defendant argues that Professor Zettler is not qualified to render an opinion on how long the shared REMS should or could have taken.

*35 Defendant improperly truncates Professor Zettler's experience. She is a lawyer, who served as associate chief counsel in the U.S. Food and Drug Administration's ("FDA") Office of the Chief Counsel, where she advised on various issues including drug safety, prescription drug advertising and promotion, clinical investigation oversight, drug labeling, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, incentives for developing antibiotics, and advisory committees. (Def.'s Omnibus Mot., Ex. 1, Patricia Zettler Rep. ("Zettler Rep."), ¶ 1.) While at the FDA, REMS were one of her areas of specialization, and she "regularly met with agency personnel in the Center for Drug Evaluation and Research (CDER) involved with REMS, including personnel in CDER's Office of Regulatory Policy and Office of Surveillance and Epidemiology, provided advice on REMS for specific drugs and drug classes, including REMS with elements to assure safe use and single shared systems (SSRS), and reviewed and revised agency documents related to REMS." (Id. ¶ 9.) In addition, Professor Zettler specialized in prescription drug advertising and promotion, and she regularly provided advice on the FDA's policies for prescription drug advertising and promotion and whether drug companies' promotional activities violated relevant provisions of the FDCA and the FDA's implementing regulations. (Id. ¶ 10.)

After leaving the FDA, Professor Zettler served for two years as a Fellow and Lecturer at Stanford Law School where she conducted research on FDA regulation of drugs and devices and co-taught the law school's Food and Drug Law course, which covered, in part, the FDA's requirements for REMS and prescription drug advertising and promotion. (Id. ¶ 7.) She also worked as a professor at Georgia State University College of Law and, currently, at The Ohio State University College of Law, where she has continued to develop an expertise in FDA regulation, including the FDA's requirements for REMS and prescription drug advertising and promotion. (Id. ¶ 11–12.) From 2016 to 2017, Professor Zettler served as a consultant to the National Academies of Sciences, Engineering, and Medicine's Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse, where she provided advice on the FDA's authority over and the regulatory history for prescription opioids, including issues associated with REMS and prescription drug advertising and promotion.¹⁷ (Id. ¶ 11.)

Given this extensive background, I have little trouble finding that Professor Zettler may render the opinions in her report. As repeatedly emphasized, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." [Kannankeril v Terminix Int'l](#), 128 F.3d 802, 809 (3d Cir. 1997).

2. Methodology

In January 2012, the FDA asked all generic manufacturers of buprenorphine medications to collaborate with Reckitt on a single, shared REMS ("SSRS") by May 5, 2012. Given the contentious nature of the negotiations, the generic manufacturers submitted a proposed generics-only REMS, which the FDA rejected as inadequate. From that initial submission to approval, another 188 days passed due to additional deficiencies identified by the FDA. Professor Zettler opines that had Reckitt informed the FDA and the generics at the start of the REMS process, on January 12, 2012, that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted BTOD SSRS six months earlier than actual approval was obtained.

*36 Defendant contends that Professor Zettler's methodology in reaching this opinion is unreliable because the opinion rests on four assumptions: (1) the FDA would accept Reckitt's hypothetical refusal to negotiate rather than continuing to ask Reckitt to engage in negotiations; (2) after a Reckitt refusal to negotiate, it would take the FDA only twelve days to inform the generics that the FDA was willing to consider a waiver-granted SSRS, meaning that the generics could file their own REMS safety plan independent of Reckitt; (3) although the FDA had set a 120-day deadline for the submission of REMS documentation, the generics would have beaten the deadline by almost two months; and (4) instead of 188 days passing between the generics' initial submission and approval of their REMS, the time interval instead would have been only 165–175 days. Taking each assumption individually, Defendant attempts to debunk the opinion's validity and argues that Professor Zettler has no qualification or methodology by which to reach these various conclusions.

Defendant's challenge is an effort to establish facts before a jury rather than a proper Daubert attack on an expert's reliability. The Third Circuit has recognized that an expert may construct—as Professor Zettler does here—a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened ‘but for’ the defendant's unlawful activities.” ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 292 (3d Cir. 2012) (quoting LePage's Inc. v. 3M, 324 F.3d 141, 165 (3d Cir. 2003)). When certain facts underlying the “but-for” world are in dispute “experts sometimes reach different conclusions based on competing versions of the facts. The emphasis...on ‘sufficient facts or data’ is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.” Fed. R. Evid. 702, Advisory Committee's Notes (2000). In other words, Daubert “does not preclude testimony merely because it may be based on an assumption.” In re Dill Litig., 193 F.3d 613, 677 (3d Cir. 1999) amended 199 F.3d 158 (3d Cir. 2000). Rather, contentions that an expert's assumptions are unfounded go to the weight, not the admissibility, of the testimony. Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996).

I find that Professor Zettler's methodology meets the standard of reliability as she analyzed the real-world timeline of the SSRS-related activity, applied her knowledge of and experience with FDA policy and practice, and adjusted that timeline to reflect a world in which Defendant promptly refused to participate and was not involved in SSRS negotiations. Her report encompasses her review of Defendant's internal planning documents, FDA communications, and generic actions and then constructs a detailed timeline of actions by Defendant that, in her opinion, delayed approval of the REMS. (Zettler Rep. ¶¶ 118–135.) Her report also describes, based on various communications and events, the timeline for the generics' development of a single shared REMS had Defendant informed the FDA that it did not intend to participate in a single shared REMS on or about January 12, 2012. (Id. ¶¶ 136–43.) To the extent Defendant believes that Professor Zettler's underlying assumptions are factually inaccurate or disproven by the evidence, it may raise those issues on cross-examination.

F. All Opinions By Deborah Jaskot

The final expert which Defendant individually challenges is Deborah Jaskot. Ms. Jaskot is a pharmaceutical industry consultant who has overseen and submitted hundreds of ANDAs to the FDA for review and approval. Based upon her thirty-plus-years' experience in the pharmaceutical industry working on FDA regulatory matters, her knowledge of FDA regulations and practices, and her review of the evidence in this case, she offers two opinions. (Def.'s Omnibus Mot., Ex. 10, Deborah Jaskot Report (“Jaskot Rep.”) ¶ 18.) First, she avers that if the REMS and REMS-related labeling of the generics' ANDAs were approved by the FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame. (Id.) Second, she opines that Reckitt's September 25, 2012 Citizen Petition was deficient in multiple respects and the specific requests therein stood no reasonable chance of being granted. (Id. ¶ 19.) Defendant challenges both opinions.

1. Opinion on the “But-For” ANDA Approval Date

*37 Defendant first contends that Ms. Jaskot has no foundation for her opinion that “but-for” Defendant's delay during the shared REMS, generic manufacturers Amneal and Actavis would have had their ANDAs for generic tablets approved between August 22, 2012 and September 1, 2012. Defendant reasons that a condition of approval of ANDAs is that the facilities that make both the finished product and its active ingredients comply with FDA regulatory requirements, namely the “Current Good Manufacturing Practices” (“cGMPs”). (Id. ¶ 44.) According to Defendant, however, both Actavis' supplier of active ingredients and Amneal's contract manufacturing facility were not cGMP-compliant as of September 1, 2012. Specifically, Defendant notes that (1) Actavis' ANDA relied upon active ingredients supplied by a facility operated by a contract manufacturer, Macfarlan Smith, which the FDA purportedly found had “objectionable conditions and practices” during an April 2012 inspection, and (2) Amneal's supplier of buprenorphine was not compliant with FDA regulations as of October 2012.

The DPPs respond that Ms. Jaskot's review of documents and application of her experience reveal a contrary conclusion: that there would have been earlier cGMP approval of both Actavis' active ingredient supplier and Amneal's contract manufacturing

facility. The DPPs note that Ms. Jaskot details how cGMP inspections are conducted, how an FDA project manager ushers an ANDA through the FDA approval process, and why the Actavis supplier compliance status would have been found acceptable earlier had the rest of the ANDA been ready for approval between August 22 and September 1, 2012. (Def.'s Omnibus Mot. Ex. 15, Deborah Jaskot Rebuttal Report ("Jaskot Reb. Rep.") ¶¶ 59–63, 67–69.) In addition, the DPPs contend that Ms. Jaskot directly disputed that there was a compliance impediment with Amneal's contract manufacturing facility that would have prevented approval of Amneal's ANDA before September 1, 2012. (*Id.* ¶¶ 39–40.)

Faced with a similar Daubert objection predicated on disputed evidence relied upon by the expert, the Third Circuit instructed:

An expert is...permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury. It is also, as the District Court observed, a proper subject for cross-examination.... [F]actual disputes are for the jury, and [plaintiff] was perfectly free to explore on cross-examination the reliance placed by [the expert] on the disputed facts and to argue to the jury that, if it rejected the underlying factual premises of his report, it should also reject [the] expert opinion...

Walker v. Gordon, 46 F. App'x 691 (3d Cir. 2002).

Here, the parties' disagreement is a dispute of fact not an issue of reliability under Daubert. Such disputes must be resolved by a fact-finder at trial, and, as such, I decline to exclude Ms. Jaskot's testimony on this ground.

2. Opinion on Reckitt's September 2012 Citizen Petition

Defendant also challenges Ms. Jaskot's report to the extent she offers the following opinion on Defendant's Citizen Petition:

***38** It is furthermore my opinion that Reckitt Benckiser's September 25, 2012 Citizen Petition was deficient in several respects and the specific requests therein stood no reasonable chance of being granted because:

(i) RB's request that generic applicants be required to engage in the same voluntary education practices as RB had no statutory support— the applicable statutes, regulations, and FDA practices only mandate that the labeling of generic drugs mimic the involuntary mandated labeling of the corresponding brand drug (with certain minor exceptions not applicable here); and (ii) RB itself admitted that the studies upon which it was relying for its requests that (1) FDA not approve ANDAs lacking unit-dose packaging and (2) FDA determine that Suboxone tablets were discontinued for reasons of safety, were incomplete, and thus, by definition, could not satisfy FDA's statutory requirements. Therefore, it is my professional opinion that each of the three specific requests in the Petition were factually and legally baseless, and that no reasonable petitioner could expect those requests to be granted. Furthermore, if I had been in charge of overseeing the filing of Citizen Petitions at Reckitt Benckiser at the time, I would not have signed or agreed to file the September 25, 2012 Petition.

(Jaskot Rep. ¶ 19.)

Defendant contends that Ms. Jaskot's opinions are inadmissible on three grounds: (1) her opinion as to the purported "baselessness" of the Citizen Petition is an impermissible legal conclusion; (2) she admits to being unqualified to opine on the scientific basis of Defendant's Citizen Petition requests; and (3) her regulatory opinions fail to fit the undisputed facts of the case. As I agree with Defendant that this opinion is an impermissible legal conclusion, I will address only this issue.

District courts "must ensure that an expert does not testify as to the governing law of the case." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." *Id.* (citing First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d

725, 731 (3d Cir. 1981)). “[An] expert [is] not free to reach conclusions about the reasonableness of [a party’s] beliefs when such an opinion necessarily would have required an interpretation of the relevant...law.” In re Wellbutrin SR, Nos. 04-5898, 05-396, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010); see also QVC, Inc. v. MJC Am., Ltd., No. 08-3830, 2012 WL 13565, at *2 (E.D. Pa. Jan. 4, 2012) (noting that experts may not apply the resulting law to the facts of a case to draw a legal conclusion).

I addressed a similar challenge in King Drug Co. of Florence Inc. v. Cephalon, Inc., Nos. 06-1833, 06-2768, 2015 WL 6750899 (E.D. Pa. Nov. 5, 2015). In that antitrust case, the issues turned substantially on whether the litigation and settlement of a prior patent suit brought by two of the antitrust defendants was valid or whether that settlement was used to prevent later competition. Id. at *1. The defendants had sought to present expert testimony that various legal arguments they made during the patent infringement lawsuit were “reasonable” and that a reasonable litigant in the defendants’ position could have realistically expected success on the merits. Id. at *15–16. In the face of a Daubert challenge by the plaintiff, the defendants contended that the experts were not presenting a legal opinion, but rather simply opining as to the customs and practices of the industry and the objective reasonableness of the parties’ patent positions. Id. at *17. The defendants further argued that the experts provided valuable insights for the jury on the factors considered by drug manufacturers when contemplating infringement settlements. Id.

*39 I disagreed with the defendants and found that a key issue in the case was whether the prior patent litigation was objectively baseless, such that no reasonable litigant could realistically expect success on the merits, and that the baseless lawsuit furthered anticompetitive activity. Id. at *17. The proposed experts were attorneys evaluating the merits of a legal argument by applying facts to the law. Id. As such, I determined that the expert’s reasonableness opinions would “usurp the role of the jury and merely tell them which conclusion to reach as to an essential element.” Id. at *17–18.

Similarly, in In re Wellbutrin SR Antitrust Litig., *supra*, the plaintiff sought to introduce expert opinions in an antitrust case also involving a sham litigation claim. Id. at *2. The experts were attorneys who opined that the defendant could not have had a reasonable expectation of success in the litigation. Id. The court found that to the extent the experts would testify as to relevant background information, such as patent practice, patent application procedure, or other areas related to patent law that would be helpful for a trier of fact, the experts were admitted. Id. at *6. To the extent, however, that the experts testified as to governing legal standards and applied those standards to the relevant facts, the court deemed these opinions impermissible legal opinions. Id. at *7.

In response to those decisions, the DPPs rely on In re Flonase Antitrust Litig., 884 F. Supp. 2d 184, 200 (E.D. Pa. 2012). That case, like the one before me, involved alleged sham citizen petitions. Id. at 188. The defendant offered an expert opinion that the petitions were “appropriate” and had “regulatory merit.” Id. at 195–96. Considering plaintiff’s Daubert challenge, the court allowed the expert to “explain that the petitions were ‘within the FDA’s jurisdiction’ of topics properly considered in the citizen petition process” or were “within the FDA’s purview.” Id. at 197. The court further noted that the expert’s testimony on the merits of the Citizen Petitions in the context of FDA regulatory policy and practice was relevant and helpful to the trier of fact. Id. at 198. However, the court concluded that the expert could not opine on the scientific merits of the citizen petitions and could merely offer opinions from an FDA regulatory and policy perspective. Id. at 199–200.

I find that Ms. Jaskot’s opinions are more akin to the opinions excluded in King Drug and Wellbutrin than the one admitted in Flonase. Ms. Jaskot’s opinion is not that Defendant’s Citizen Petition was outside the FDA’s jurisdiction of topics or that it did not satisfy the FDA’s rules for when such petitions may be filed. Rather, the opinion is that the Citizen Petition was “[f]actually and [i]legally [b]aseless.” (Jaskot Rep. p. 24.) Ms. Jaskot posits three reasons for her conclusion. First, as to Defendant’s request that the FDA not approve ANDAs that did not include a targeted pediatric exposure education program, Ms. Jaskot asserts that the studies relied upon by Defendant were insufficient and that the authority cited by Defendant did not legally support its request. (Id. ¶¶ 123–24.) Second, as to Defendant’s request that the FDA refrain from approving ANDAs that lack child-resistant unit-dose packaging, Ms. Jaskot opines that Defendant provided inadequate evidence to support this request. (Id. ¶¶ 125–26.) Third, as to Defendant’s request that the FDA not approve any ANDA for buprenorphine/naloxone tablets until it determined whether Defendant’s decision to discontinue the tablet was for safety reasons, Ms. Jaskot opines that the study relied upon by Defendant to pull its tablet from the market was inherently flawed and, therefore, Defendant did not have “a sound scientific basis to

support the actions requested in the Petition.” (*Id.* at ¶¶ 127– 33.) Ms. Jaskot then concludes that “[Defendant]’s Petition was not supported by evidence. Based on my many years of experience in industry evaluating and responding to citizen petitions, it is my professional opinion that [Defendant] did not have sound scientific basis for each of the requests stated in the Petition, that the Petition was factually and legally baseless, and no reasonable petitioner could expect the Petition to be granted.” (*Id.* ¶ 133.)

*40 Although Ms. Jaskot attempts to couch each of her statements in terms of whether the Citizen Petition conformed to the regulations governing the filing of citizen petitions, her opinion is, at its core, a pure legal conclusion as to whether the Citizen Petition had merit. This is not permissible. As one of the key issues in this case is whether Defendant’s Citizen Petition was factually and legally baseless and used entirely for anticompetitive purposes, I find that Ms. Jaskot’s opinion is a legal opinion that usurps the jury’s role in applying the law to the facts.

VI. DEFENDANT’S MOTION TO EXCLUDE PLAINTIFFS’ EXPERT OPINIONS ASSERTING OR RELYING UPON ASSERTIONS THAT ALLEGED RECKITT SAFETY MESSAGES WERE “FALSE,” “MISLEADING,” “DISPARAGING,” “FABRICATED,” “FRAUDULENT,” “SHAM,” OR “DECEPTIVE”

Defendant also seeks to preclude any of Plaintiffs’ experts from relying on the assumption that Defendant’s alleged safety claims were false, misleading, disparaging, fabricated, fraudulent, sham, or deceptive, including: (1) the DPPs’ economist experts’ assumption that Defendant’s safety claims were false in order to prove that Defendant’s alleged conduct was anticompetitive and resulted in measurable damages; and (2) Plaintiffs’ experts’ assumption that the allegedly false safety claims influenced the markets.

Proper consideration of this motion requires a more fulsome discussion of both the background of this issue and Defendant’s argument. As set forth above, Plaintiffs contend that as part of Defendant’s overall efforts to keep generic buprenorphine/naloxone tablets off the market and switch the market demand from tablets to branded film, Defendant developed a “safety story.” According to Plaintiffs, Defendant repeatedly and without evidence claimed—both in marketing and promotion and in a Citizen Petition to the FDA—that tablets were more prone than film to a risk of pediatric exposure and to misuse, abuse, and diversion. Plaintiffs’ theory posits that via this safety story, Defendant attempted to sway physicians into prescribing only film and to impede FDA approval of generic tablets.

According to Defendant, however, the veracity of its “safety” claims are backed by substantial unrefuted evidence. In its current Motion, Defendant asserts that none of Plaintiffs’ expert opinions—aside from Professor Zettler’s inadmissible legal opinion—affirmatively state that film does not offer safety advantages relative to tablets. Absent such evidence, Defendant asserts that none of Plaintiffs’ experts can assume the falsity of Defendant’s alleged promotional statements regarding damages or impact on the market. Ultimately, Defendant seeks to preclude all of Plaintiffs’ experts from characterizing Defendant’s alleged marketing claims (including claims relating to safety, pediatric exposure, abuse, diversion, or misuse) as “false,” “misleading,” “disparaging,” “fabricated,” “fraudulent,” “unfounded,” “sham,” “baseless,” “deceptive,” or the like, and to strike any expert testimony that relies on such assumptions.

Defendant relies on five core assumptions: (a) Plaintiffs bear the burden of affirmatively proving the falsity of Defendant’s safety statements about Suboxone products; (b) no Plaintiff expert testifies or is qualified to testify that the statements were actually false; (c) Plaintiffs’ expert Patricia Zettler cannot testify that the statements were “false” under FDA standards; (d) falsity cannot be proven through lay testimony or evidence; and (e) therefore, no expert may rely on the presumed falsity of Defendant’s safety statements when rendering an opinion. I address each of these assumptions individually.

A. Whether Plaintiffs Must Affirmatively Prove that the Safety Statements Were Untrue

*41 Defendant’s first assumption turns on the definition of “false and misleading.” In refuting Plaintiff’s claims of false, disparaging, or fabricated safety claims, Defendant relies on a dictionary definition of “false” and “misleading” and contends

that Plaintiffs must affirmatively prove that the safety statements at issue were untrue. Because Defendant argues that Plaintiffs have failed to meet this burden, Defendant presses that Plaintiffs' expert economists may not rely on such statements to prove antitrust impact or damages.

It is well established, however, that "[a]ntitrust analysis must always be attuned to the particular structure and circumstance of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation." [Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP](#), 540 U.S. 398, 411, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004). Therefore, I must look to the FDA's marketing rules to determine whether Defendant's safety statements were indeed "false" or "misleading."

The FDA defines "marketing" as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. [Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc.](#), 499 F.3d 239, 243 (3d Cir. 2007) (citing 21 C.F.R. § 202.1(1)), vacated on other grounds, 556 U.S. 1101, 129 S.Ct. 1578, 173 L.Ed.2d 672 (2009). "Although advertising may also serve as a mechanism to distribute safety information about a drug, its primary purpose—unlike labeling is not to promote safety but rather to promote market expansion." *Id.*

Under the relevant regulations

An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

...

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

...

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

...

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

21 C.F.R. § 202.1(e)(6).

Thus, the standard for whether the statements at issue here are "false, lacking in fair balance, or otherwise misleading" does not turn, as Defendant urges, on whether the statements are untrue, but rather on whether Defendant had substantial evidence or substantial clinical experience to support those statements. "Substantial evidence" is defined as "adequate and well-controlled investigations, including clinical investigations...by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses." 21 C.F.R. § 202.1(e)(4)(ii)(b). "Substantial clinical experience" means "substantial clinical experience adequately documented in medical literature or by other data...on the basis of which it can be fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses." *Id.* at § 202.1(e)(4)(ii)(c). Indeed, FDA officials have explained:

*42 Promotional labeling or advertising is considered false or misleading if it contains claims that are not supported by substantial evidence. This includes, for example, claims about product uses (indications), dosing, and advantages over other products or interventions. Thus, comparative claims of effectiveness or safety in promotional labeling and advertising generally must be supported by substantial evidence from adequate and well-controlled trials that demonstrate that the drug will have the claimed effect (for example, superiority over another treatment).

To be considered “substantial evidence” of effectiveness, the trials would generally have to been designed to provide a fair and valid head-to-head comparison of the treatments in question (for example, the doses of compared products and treatment duration should be clinically comparable)....

(Pls.’ Resp. to Def.’s Safety Mot., Ex. 23, Joseph P. Griffin, et al., “Regulatory Requirements of the Food and Drug Administration Would Preclude Product Claims based on Observational Research,” 31 *Health Affairs* 2188, 2190 (2012).)

Defendant attempts to avoid these regulations by positing two arguments. First, it contends the FDA advertising regulations have little bearing on the issue here because violations of the FDCA or its related regulations, even if proven, “do nothing to illuminate whether an antitrust violation occurred.” (Def.’s Mot. to Preclude Expert Reliance on Allegedly False Safety Messages (“Def.’s Safety Mot.”) 12.) Citing to the Third Circuit’s decision in *Philadelphia Taxi Assoc., Inc. v. Uber Techs., Inc.*, 886 F.3d 332 (3d Cir.), *cert denied*, — U.S. —, 139 S. Ct. 211, 202 L.Ed.2d 126 (2018), Defendant contends that even if a defendant was “able to cut costs by allegedly violating...regulations, [the plaintiffs] cannot use the antitrust law to hold [the defendant] liable for these violations absent proof of anticompetitive conduct.” *Id.* at 340.

Defendant’s citation, however, avoids the very next portion of the sentence in *Philadelphia Taxi*, which states that “[e]ven unlawful conduct is ‘of no concern to the antitrust laws’ *unless it produces an anticompetitive effect.*” *Id.* (quotations omitted) (emphasis added); see also *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 958927, at *16 (D.N.J. Oct. 29, 2015) (allowing antitrust plaintiff to prove violation of FDA regulations as part of an overall anticompetitive scheme). As I noted previously, “a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable.” *In re Suboxone Antitrust Litig.*, 13-2445, 2017 WL 36371, at *8 (E.D. Pa. Jan. 4, 2018) (citing cases); see also *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) (“If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.”).

The allegation here is multi-layered: Defendant’s repeated and willful violations of FDA advertising regulations in the form of unsubstantiated or “false” warnings about the comparative safety benefits between film and tablets—combined with the increase in the price of tablets and decrease in the price of film, the introduction of *Suboxone* film onto the market, the removal of *Suboxone* tablets from the market several months prior to generic approval, delay in the shared REMS, and an improper citizen petition—all contributed to a pattern of anticompetitive conduct resulting in an anticompetitive effect. To that end, Plaintiffs need not affirmatively prove that Defendant’s marketing statements were “false” or “misleading” in the sense of being untrue. Rather, they need only prove that, at the time those statements were made, Defendant did not have substantial evidence or statistically significant data from head-to-head clinical trials.

*43 Defendant’s second effort to avoid the regulatory definition given to the terms “false” and “misleading” cites the Merriam-Webster Dictionary definition of “false” and “misleading” and asserts that these terms—as well as the terms “fabricated,” “fraudulent,” “sham,” or “deceptive”—have well-understood colloquial meanings that signify dishonesty and deception and suggest that Defendant’s safety claims were wrong. Defendants posits that a juror will not fully understand in the context of the case that the words “false” or “misleading,” as used by Plaintiffs’ experts, simply mean that “at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials.”

Defendant’s concerns are nothing more than a fear that the jurors will not comprehend its theory of the case. To the extent that a witness testifies that certain marketing statements were false, misleading, or otherwise deceptive, counsel may use opening

statements, closing statements, direct examination, or cross-examination to clarify the meaning of those terms. If a witness suggests that the marketing statements had the colloquial definition of false, counsel may use cross-examination to underscore that the witness has no such actual knowledge. Finally, Defendant will be free to request appropriate jury instructions on this issue. The mere possibility of confusion does not constitute grounds for disregarding the clear statutory and regulatory meaning of “false and misleading.”

In short, to establish that Defendant's marketing and promotional statements comparing the safety of film and tablets were deceptive—as part of Defendant's overall anticompetitive scheme to prevent the intrusion of generic tablets on the market—Plaintiffs need only prove that the promotional statements were “false and misleading” as defined by the FDA. Under the FDA regulations, Defendant was not permitted to make statements about or offer comparisons between its drug and other drugs unless it had, at the time the statements were made, substantial evidence or substantial clinical experience to support those statements. To the extent Defendant did not have such evidence at the time it made those statements, Plaintiffs may properly rely on Defendant's actions—as part of an overall antitrust scheme—to establish an anticompetitive effect.

B. Whether Plaintiffs Have Expert Testimony to Support Their Claim that the Statements Were “False and Misleading

Defendant's second assumption asserts that none of Plaintiffs' experts can opine that film does not offer safety advantages relative to tablets. Defendant reasons that only two of Plaintiffs' experts—Drs. Westreich and Jewell—claim to possess expertise allowing them to analyze the scientific and epidemiological evidence relating to the safety of Suboxone film and Suboxone tablets. Both witnesses, however, clearly acknowledge that they will not express an opinion as to whether or not film would pose fewer safety risks to public health as compared to Suboxone tablets and that they did not make affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric. (Westreich Dep. 189–90; Jewell Dep. 22–25.) Rather, these witnesses conclude that there is simply not enough evidence to determine one way or another whether film offers diminished susceptibility to risks of pediatric exposure, or use, misuse and diversion. According to Defendant, such testimony is insufficient to establish that Defendant's statements were “false” or “misleading.”

Plaintiffs, however, do not purport to offer an expert to directly rebut Defendant's statements that film poses fewer safety risks than tablets. Rather, Plaintiffs' experts seek to testify that Defendant's safety claims were not grounded in fact and science and were not supported by substantial evidence or substantial clinical studies. To that end, Plaintiffs proffer the testimony of Nicholas Jewell who (a) considers, from a statistical perspective, the data, analysis, and conclusions regarding the comparative safety of the film formulation of Suboxone versus the tablet formulation of Suboxone as set forth in two articles upon which Defendant relied, RADARS I and RADARS II; and (b) comments on the reliability, from a statistical perspective, of certain analyses purporting to compare the persistency and relapse rates of patients taking the formulation of Suboxone or the tablet formulation. (Jewell Rep. ¶ 9.) Based on multiple factors detailed throughout his report, Dr. Jewell opines that the conclusions set forth in the RADARS I and RADARS II articles were not reliable and, therefore, any claims by Defendant that tablets were less safe than film were “without substance statistically.” (*Id.* ¶¶ 10–15.)

*44 Plaintiffs also offer Dr. Laurence Westreich who connects the “false and misleading” statements to the alleged anticompetitive impact. Dr. Westreich opines that “[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical associations, and interacting with other doctors,” he, as the “average, reasonable” physician, would be impacted and influenced by Reckitt's claims about the tablets' dangers, would have maintained an anti-tablet bias after generic tablets became available, and would have factored information about impending tablet withdrawal into treatment decisions. (Westreich Rep. ¶¶ 235–70.) In addition, Dr. Westreich offers an assessment, based on his experience in peer review, of whether the circumstances under which certain or Reckitt's studies were prepared violated well-established safeguards on independent, accurate, and reliable studies. (*See, e.g.*, Westreich Rep. ¶ 103 (“Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry.”); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 (“From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis.”); ¶ 155 (“documents extrinsic to the paper also show that it was finalized under

extraordinary time pressures, which may also have contributed to data inaccuracies.”); ¶ 189 (“as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse and Diversion study.”).) None of these statements/opinions speak to false safety claims.

In short, neither Dr. Jewell nor Dr. Westreich opines, from a scientific standpoint, that Defendant's safety claims were wrong. They need not do so under FDA standards. Rather, these experts provide an opinion that the underlying studies on which Defendant based its statements did not constitute “substantial evidence”—*i.e.*, they were not “adequate and well-controlled investigations, including clinical investigations...by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses.” 21 C.F.R. § 202.1(e)(4)(ii)(b). In turn, I find that the opinions of these experts provide an adequate foundation for the assertion that Defendant's safety messages were false and misleading.

C. Whether Professor Zettler May Opine that Defendant's Statements Were “False” or “Misleading”

Plaintiffs also offer Professor Patricia Zettler who opines in part that (a) Reckitt's promotion of the Suboxone film as less prone to misuse, diversion, and pediatric exposure than the Suboxone tablet was false or misleading in violation of the FDCA and FDA's regulations because the claims were not supported by statistically significant data at the time; and (b) if she were an attorney counseling a drug sponsor client in the position of Reckitt, she would have advised her client not to make such safety claims. Specifically, she states:

Reckitt's promotion of the Suboxone Film product as less prone to misuse, diversion, and pediatric exposures than the Suboxone Tablet product was false or misleading in violation of the FDCA and FDA's regulations, and inconsistent with FDA policies, because, at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials adequately designed to compare the two products or equivalently robust data.

(Zettler Rep. ¶ 19(c).)

Defendant posits four challenges to Professor Zettler's opinion. First, it again challenges her qualifications. Second, it asserts that her opinions constitute improper legal conclusions. Third, it argues that her legal opinions are irrelevant to antitrust liability. Finally, it claims that Professor Zettler's legal opinion rests on a botched legal analysis.

1. Qualification

Defendant first alleges that Professor Zettler is not qualified to assess whether any safety claim is either proven or substantiated, as she is a lawyer without a professional background in epidemiology, statistics, or medicine. Professor Zettler, however, makes no attempt to look at scientific evidence or scientifically study whether film has any safety benefits as opposed to tablet products. Accordingly, I need not address her qualifications from that perspective. As set forth in detail *supra*, I find Professor Zettler qualified under *Daubert* to render the opinions set forth in her report.

2. Improper Legal Conclusion

*45 Defendant next argues that Professor Zettler's opinion that alleged safety claims did not comply with the FDCA and FDA regulations is an improper legal conclusion. Defendant urges that because Professor Zettler explores the legal question of

whether Defendant's marketing claims applied to her interpretation of the governing regulations and statutes, it is pure exercise in statutory interpretation and not appropriate for expert review.

As explained in detail above, expert witnesses are prohibited from rendering a legal opinion because “it would usurp the District Court's pivotal role in explaining the law to the jury.” [Berkeley Inv. Grp., Ltd. v. Colkitt](#), 455 F.3d 195, 217 (3d Cir. 2006). Nonetheless, “expert testimony that implicates or touches on legal issues is not *per se* inadmissible.” [Comcast Cable Commc'ns, LLC v. Sprint Commc'ns Co.](#), 203 F. Supp. 3d 499, 546 (E.D. Pa. 2016). “Courts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper.” [In re Wellbutrin SR Antitrust Litig.](#), Nos. 04-5898, 05-396, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010) (citing cases). As observed by the court in [In re Fosamax Prods. Liab. Litig.](#), 645 F. Supp. 2d 164 (S.D.N.Y. 2009):

A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury. An expert may offer testimony embracing an ultimate issue of fact that the jury will decide. [Fed. R. Evid. 704\(a\)](#). Cross-examination and competing expert testimony by Merck's regulatory experts will ensure that the jury carefully weighs her testimony.

[Id.](#) at 190–91.

Numerous courts have found that “the testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury.” [In re Mirena IUD Prods. Liab. Litig.](#), 169 F. Supp. 3d 396, 478–79 (S.D.N.Y. 2016) (citing [Wells v. Allergan, Inc.](#), No. 12-973, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) (finding expert testimony about FDA regulations would not “usurp” the role of the trial judge); [In re Yasmin & YAZ \(Drospirenone\) Mktg., Sales Practices & Prods. Liab. Litig.](#), No. 09-2100, 2011 WL 6302287, at *25 (S.D. Ill. Dec. 16, 2011) (discussing FDA regulations and finding that “[t]o the extent [the expert] does offer legal conclusions, the Court finds that [the expert's] testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. [The expert's] testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not [the expert] nor any other witness, will instruct the jury on the law in this case.”); [In re Fosamax](#), 645 F. Supp. 2d at 191 (denying motion to preclude expert from “testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith”). In particular, courts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA. *See, e.g.,* [Wolfe v. McNeil-PPC, Inc.](#), 881 F. Supp. 2d 650, 659–60 (E.D. Pa. 2012) (experts permitted to testify that defendants withheld information from FDA and failed to conduct a proper safety analysis); [Bartoli v. Novartis Pharm. Corp.](#), No. 13-724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014 (finding that expert could opine on the reasonableness of defendant's conduct in its interactions with the FDA and compliance with FDA regulations, including defendant's interactions with FDA with respect to labels and warnings); [Pfizer v. Teva Pharms. USA, Inc.](#), 461 F. Supp. 2d 271, 278–79 (D.N.J. 2006) (finding admissible expert testimony regarding FDA regulation of labeling, advertising, and promotion of prescription drugs, and to what extent the pharmaceutical company complied with those requirements).

*46 Here, the key issue in this case is not whether Defendant violated FDA regulations regarding its marketing of film and its safety statements regarding tablets.¹⁸ Rather, it is whether Defendant made unsupported safety claims regarding Suboxone tablets in an effort to divert the market away from tablet prescriptions and further its alleged anticompetitive scheme. To that end, Professor Zettler engages in an extensive discussion of the regulations regarding advertising and promotion in the prescription drug industry. Specifically, she states:

- Under FDA regulations, a drug sponsor generally cannot make claims regarding the safety and effectiveness of its drug product unless and until those claims are supported by sound scientific evidence at the time they are made, regardless of whether such claims are made in writing or orally. (*Id.* ¶ 51.)
- The requirement to comply with FDA marketing regulations and policies is well known in the pharmaceutical industry. Promotional materials provided to healthcare professionals on behalf of a company should make claims about a product only when substantiated (*Id.* ¶ 144.)
- Defendant understood that FDA and FDCA promotional materials had to have statistically significant data supporting the claims made therein in order to avoid being “false, lacking in fair balance, or otherwise misleading.” (*Id.* ¶¶ 145–51.)
- From 2009 to August 2010, Defendant actively promoted [Suboxone](#) Film as safer than [Suboxone](#) tablets because it had lower risks of abuse, diversion, and misuse and because it had a lower risk of unintended pediatric exposure. (*Id.* ¶¶ 152–54.)
- At the time Defendant was issuing those statements, there was insufficient data to support the accuracy of claims that the Film product was less prone to misuse, diversion, and pediatric exposures than the tablet product was. FDA officials on multiple occasions concluded that the existing evidence did not support those assertions, and Defendant's own documents and testimony show that the company was not aware of sufficient scientific evidence to support its claims that Film was safer than tablets. (*Id.* ¶¶ 155–60.)

Such testimony may assist a jury not only in understanding the federal regulations and what they require, but also how Defendant's own testimony and admissions reveals that its communications did not comply with FDA and FDCA standards for prescription drug promotional materials.

*47 However, the next two paragraphs of Professor Zettler's report cross the line into an inadmissible legal opinion when she reaches her final conclusions that: (1) Defendant's claims that film was less prone to misuse, diversion, and pediatric exposures than tablets were false or misleading under the FDCA and FDA regulations, in that the claims were not substantiated by sufficient scientific evidence at the time they were made, and (2) had Defendant been her client, she would have advised it that it should not make claims that film was safer than tablets because such claims would violate FDA requirements in the absence of head-to-head clinical trials adequately designed to compare the products or equivalently robust scientific evidence. (*Id.* ¶¶ 161–62.) Such conclusions are for the jury to reach upon application of the law to the facts. Therefore, to the extent Professor Zettler seeks to offer these ultimate opinions, her testimony will be excluded.

3. Relevance

Defendant's third challenge to Professor Zettler's opinion contends that her opinions are irrelevant. It posits that Plaintiffs cannot bring a private cause of action under the FDCA, and that violations of the FDCA or its regulations, even if proven, do nothing to illuminate whether an antitrust violation has occurred. Thus, Defendant concludes that testimony about alleged FDCA violations tells us nothing about whether such conduct had an anticompetitive effect.

This argument represents yet another attempt by Defendant to sever Plaintiffs' theory into several individual causes of action. As I have previously noted, false or misleading disparagement of another company's product “can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.” [In re Suboxone Antitrust Liab.](#), 64 F. Supp. 3d 665, 682 (3d Cir. 2014) (quotations and citations omitted). I further remarked that “[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film.” *Id.*; see also [Int'l Travel Arrangers, Inc. v. Western Airlines, Inc.](#), 623 F.2d 1255, 1268 (8th Cir. 1980) (holding that alleged monopolist's false, misleading, and deceptive advertising against another company for the purpose of preventing any effective competition was an unreasonable restraint of trade). Thus, although Plaintiffs cannot use antitrust law to hold Defendant liable

for stand-alone violations of administrative regulations or unlawful conduct, those violations are relevant to Plaintiffs' proof of an overarching scheme that had an anticompetitive effect. I decline to exclude Professor Zettler's report on this ground.

4. Reliability

Defendant's final challenge to Professor Zettler's analysis contends that it rests upon a "botched legal analysis." (Def.'s Safety Mot. 13.) In support of this position, Defendant sets forth three arguments.

First, Defendant contends that Professor Zettler's analysis is untethered to the text of the FDCA because she relies on a provision of the FDCA that a drug is misbranded if "[i]ts labeling is false or misleading." 21 U.S.C. § 352(a). But, according to Defendant, the definition of "labeling" is limited to "written, printed, and graphic material," 21 U.S.C. § 321(m), and almost all of the alleged communications Professor Zettler deems "false and misleading" are oral discussions or internal memorandum.

Professor Zettler's opinion, however, is not limited to "labeling," but rather focuses on "prescription drug advertising and promotion." (Zettler Rep. ¶ 145.) As noted above, the FDA defines marketing as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; *and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media.* [Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc.](#), 499 F.3d 239, 243 (3d Cir. 2007) (emphasis added) (citing 21 C.F.R. § 202(l)(1)); *see also* [In re Schering-Plough Corp. Intron/Temodar Consumer Class Action](#), No. 06-5774, 2009 WL 2043604, at *2 (D.N.J. July 10, 2009) ("In addition to regulating the labeling of prescription drugs, the FDA is also empowered under the FDCA to regulate prescription drug advertising and marketing, *including marketing directed at physicians and the medical community at large.*") (emphasis added); [IMS Health, Inc. v. Ayotte](#), 490 F. Supp. 2d 163, 168 (D.N.H. 2007) (noting that the FDA is "authorized to take enforcement action against companies that use false and misleading advertising materials....This regulatory authority also extends to oral misrepresentations by sales representatives."). Thus, I find no merit to Defendant's first argument.

*48 Second, Defendant contends that courts construing the FDCA's misbranding provisions in light of the protections of the First Amendment have held that an accusation of misbranding cannot be established absent proof that a claim was untrue. The cases cited by Defendant in support of this proposition are distinguishable, as they involve criminal prosecution of a drug company for violations of the branding regulations. *See* [United States v. Caronia](#), 703 F.3d 149, 162 (2d Cir. 2012) (finding that FDCA's misbranding provisions do not criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives "because such a construction—and a conviction obtained under the government's application of the FDCA—would run afoul of the First Amendment."); [Amarin Pharma, Inc. v. U.S. Food & Drug Admin.](#), 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (holding that under [Caronia](#), the FDA may not bring a misbranding action against a manufacturer based on truthful promotional speech alone). This case, by contrast, is not a misbranding action brought by a governmental entity, but rather an antitrust action alleging that Defendant's "false and misleading" promotion—as defined by the applicable regulations—was part of a broader antitrust scheme to preclude generic competition. Defendant offers no authority for the proposition that such an action is violative of the First Amendment.

Finally, Defendant contends that Professor Zettler relies on a regulation relating to "advertisement[s] for a prescription drug," which states that comparative claims should be demonstrated "by substantial evidence or substantial clinical experience." According to Defendant, however, Professor Zettler does not analyze any advertisements. Moreover, Defendant asserts that no authority requires head-to-head clinical trials in the promotional advertising sphere, and that FDA guidance provides that promotional claims are subject only to the lesser "competent and reliable information" standard.

These arguments are not a basis for exclusion of Professor Zettler's testimony—indeed, they highlight its necessity. FDA regulations and their application are confusing, such that a jury cannot be expected to understand them without expert assistance. Flaws in Professor Zettler's discussion of FDA regulatory standards are easily and more appropriately addressed on cross-examination or through Defendant's own rebuttal experts.

5. Conclusion as to Professor Zettler

In sum, although Professor Zettler cannot offer an opinion as to whether Defendant's promotional statements were “false and misleading,” she may provide expert testimony regarding the requisite standards under the regulations. Additionally, she may discuss, based on her review of relevant documents, what type of support Defendant had for its safety claims.

D. Whether Falsity May Be Proven Through Lay Testimony or Evidence

Defendant's next assumption rests on the notion that Plaintiffs cannot “use non-expert testimony provide a foundation for their experts’ assumptions on the supposed falsity of Reckitt's alleged safety claims.” (Def.’s Safety Mot. 17.) Defendant goes on to cite numerous cases for the proposition that courts have required expert testimony in pharmaceutical product liability cases on issues of causation. They assert that comparative pharmaceutical safety—such as comparisons between [Suboxone](#) tablet and [Suboxone](#) film—is beyond the experience and understanding of lay jurors. Yet, according to Defendant, Plaintiffs have no expert testimony to this issue. Moreover, Defendant challenges Plaintiffs’ reliance on an FDA “General Advice letter” from 2010 stating that the FDA did not agree that Reckitt had proven that film's packaging “provides meaningful incremental protection against pediatric exposure.” (Def.’s Safety Mot., Ex. 47.)

Defendant's analysis is flawed for two reasons. First, and as repeatedly set forth above, in order to establish that Defendant's safety claims were false and misleading, Plaintiffs need not affirmatively prove that tablets were as safe or safer than film. Rather, under the FDA regulations, they need only establish that Defendant lacked a reliable scientific basis on which to make their safety claims. To that end, Plaintiffs have proffered expert witness testimony from Professor Jewell and Dr. Westreich, both of whom opine as to the reliability of the studies on which Defendant based its safety claims. Moreover, Plaintiffs offer Professor Zettler to describe FDA marketing regulations and discuss what constitutes substantial evidence to support a comparative pharmaceutical claim. Plaintiffs need not offer any expert testimony to prove that film was not, in fact, safer than tablets.

*49 Second, Plaintiffs have put forth documentary evidence that Defendant lacked a scientific basis for its claim, including (1) the FDA's June 2009 internal memorandum that Defendant's film NDA “[did] not provide evidence to compare the safety profile of the [Suboxone](#) strip to the [Suboxone](#) tablet”; (2) the FDA's 2010 letter stating that the FDA did not agree that Defendant had proven that film's packaging provided “meaningful incremental protection against pediatric exposure” because Defendant provided “no data” to support this claim;¹⁹ and (3) the FDA's August 2010 medical review stating that although Defendant “has implied that [Film] may represent an advantage over the current tablet products with respect to diversion...there is no basis for comparison, [and] there does not appear to be any reason to conclude that this formulation rendered the study drug particularly resistant to diversion.” (Pls.’ Resp. to Safety Mot., Ex. 4 ¶ 144; Ex. 1 ¶ 96; Ex. 12 ¶ 156.) To the extent Defendant can rebut this evidence at trial, it is free to do so, and the jury can choose which story to credit.

Simply put, such “non-expert” evidence provides a foundation on which Plaintiffs can claim that, under the FDA regulations, Defendant's safety claims were “false and misleading.”

E. Whether Plaintiffs’ Experts on Antitrust Impact and Damages May Rely on Assertions that Defendant's Safety Messages Were False or Misleading

As a culmination of its motion, Defendant contends that Plaintiffs’ experts cannot rely on the unproven assumption that film safety claims are false. According to Defendant, Plaintiffs’ causation and damages experts purport to rely on a conclusion that has not been substantiated by any Plaintiff expert: that film does not provide safety benefits with respect to pediatric exposure, abuse, or diversion. Arguing that it is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record,²⁰ Defendant requests that I preclude all of Plaintiffs’ experts from characterizing Defendant's alleged marketing claims as “false,” “misleading,” “disparaging,” “fabricated,” “fraudulent,” “unfounded,” “sham,”

“deceptive,” or the like, and strike all such testimony contained within the reports of Plaintiffs’ experts Professor Zettler, Dr. Berndt, Dr. Conti, Dr. Emch, Ms. Jaskot, Dr. Lamb, Ms. Tso, and Dr. Verscharen.

Defendant’s request, however, asks me to rule on an issue of fact, *i.e.*, whether Defendant had substantial evidence to support its safety claims at the time they were made. Neither Daubert motions nor summary judgment motions are proper vehicles for such a request. Rather, “[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination.” Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002). Thus, to the extent that Plaintiffs can prove at trial that Defendant’s safety claims were “false and misleading” as defined in the FDA and FDCA regulations, Plaintiffs’ causation and damages experts may analyze these claims, in conjunction with the remainder of Defendant’s challenged conduct, to opine on the ultimate effect on the market and resulting damages.

VII. CONCLUSION

*50 I will grant the Phase I Daubert Motions in part and deny them in part as detailed in this Opinion. An appropriate Order follows.

All Citations

Slip Copy, 2020 WL 6887885

Footnotes

- 1 Reckitt is currently known as Indivior, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. Although Indivior is technically the named defendant in this case, the pleadings and many of the relevant exhibits use the name “Reckitt.”
- 2 Rather than re-hashing the complicated regulatory background and factual basis of this case, I incorporate by reference the history set forth in my prior decision certifying a class for both the DPPs and EPPs. In re Suboxone, 421 F. Supp. 3d 12 (E.D. Pa. 2019), aff’d, 967 F.3d 264 (3d Cir. 2020). To the extent necessary, I will discuss facts that are pertinent to each particular expert at issue.
- 3 As explained in the class certification decision, REMS is a Risk Evaluation and Mitigation Strategy to “manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks. <https://www.btodrems.com/SitePages/Welcome.aspx>. The FDA can also require that generic sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a Single Shared REMS program (“SSRS”), which is a single REMS program to be used by both the sellers of the brand drug and AB-rated generic equivalents.
- 4 “An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food, Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator’s judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483->

frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form% 20483,FD%26C)%20Act%20and%20related%20Acts.

- 5 Dr. Fleischer's qualifications render this case distinguishable from the Tenth Circuit case of [TK-7 Corp. v. Estate of Barbouti](#), 993 F.2d 722 (10th Cir. 1993) on which the DPPs rely. In that case, the court found that an expert opinion was inadmissible where the expert “failed to demonstrate any basis for concluding that another individual's opinion on a subjective financial prediction was reliable, other than the fact that it was the opinion of someone he believed to be an expert who had a financial interest in making an accurate prediction.” [Id.](#) at 732.

Unlike [TK-& Corp.](#), Dr. Fleischer is qualified and has indicated that he independently reached his opinion. He merely confirmed and corroborated that opinion with Dr. Patel and Mr. LoPiccolo.

- 6 The DPPs contend that Dr. Fleischer admitted at deposition that because Ms. Kinard's company, PPD, was in charge of developing and launching the website and call center, Ms. Kinard was in a better position to testify as to how quickly the go-live requirements could have been completed. (Fleischer Jan. 7, 2020 Dep. 121:4–8.)

However, an expert will not be excluded “simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” [Holbrook v. Lykes, Bros. S.S. Co.](#), 80 F.3d 777, 782 (3d Cir. 1996). Rather, in the event that Dr. Fleischer and Ms. Kinard offer conflicting testimony on this subject at trial, it will be within the province of the jury to weigh their credibility, taking into consideration Dr. Fleischer's admission that Ms. Kinard is more qualified.

- 7 The States also argue that Dr. Curtis is also not qualified to draw conclusions about patients’ or physicians’ preferences from a medical perspective because she is not an expert in opioid use disorder and has no medical training. Defendant, however, does not offer Dr. Curtis as a medical expert, but rather as a statistical and consumer/marketing research expert. As such, I need not address this argument.

- 8 (See States’ Mot., Ex. B, Expert Rebuttal Report of Ernst Berndt (“Berndt Rebuttal Rep.”) ¶¶ 76–79 (“For example, the 2011 [Suboxone](#) Film Post Launch Monitor excludes potential respondents that never took Film, so their preferences for taking and remaining on tablets are also excluded from the analysis....This introduces sampling bias in the results, because the outcomes are based upon a non-representative sample of the population that would, on average, already exhibit a preference for Film.”); States’ Mot., Ex. J, Expert Report of Nicholas Jewell (“Jewell Rep.”), ¶ 63 (“It is clear that physicians’ opinions and practices were the driver in providing film experience for a significant number of respondents, a factor that has an indeterminate influence on patients’ responses. However, it is reasonable to assume that this phenomenon will bias preference results in favor of film as the imposition of film by a physician brings with it the implicit (if not explicit) endorsement of the physician, potentially affecting a patient's preference for one formulation over the other.”).)

- 9 Specifically, Piano commented: “We want to stress that the ratio of HTH [Here to Help] enrolled physicians to non-HTH enrolled physicians was 10 to 3 in this research: this inequality increased branded over generic preference in this sample compared to what would likely occur in the market. In forecasting preference shares this inequality overstates the share preferences for branded!” (States’ Mot., Ex. 24.)

- 10 RADARS refers to the Researched Abuse, Diversion, and Addiction-Related Surveillance program. (Jewell Rep. at n. 1.) RADARS I looked at the “Root causes, clinical effects, and outcomes of unintentional exposures to [buprenorphine](#) by young children.” ([Id.](#)) RADARS II looked at “Abuse and diversion of [buprenorphine](#) sublingual tablets and film.” ([Id.](#) at n.2.)

- 11 I do not find Defendant's cited cases persuasive as each case involved either (a) an expert who admitted that he/she did not prepare certain portions of the report or (b) there was clear and convincing evidence that the expert did not prepare the report. I have neither scenario before me. See, e.g., [Numatics v. Balluff](#), 66 F. Supp. 3d 934, 941 (E.D. Mich. 2014) (excluding expert report where expert conceded at deposition that defendant's counsel wrote the expert report

and the expert reviewed the draft of the 64-page report for only a couple of hours before signing it); DataQuill Ltd. v. Handspring, Inc., No. 01-4635, 2003 WL 737785, at *4 (N.D. Ill. Feb. 28, 2003) (excluding expert testimony where expert admitted that plaintiff's counsel actually typed his report, large quantities of plaintiff's interrogatory responses appeared verbatim in the expert report, and expert did not even follow a proper infringement analysis); Play Visions, Inc. v. Dollar Tree Stores, Inc., No. 09-1769, 2011 WL 2292326, at *9 (W.D. Wash. June 8, 2011) (excluding expert report where expert admitted at deposition that counsel had just asked questions of the expert and filled in the answers on the report and that the expert did not see the final report until after it was circulated to the defendants; expert then submitted a "change" sheet after reviewing his deposition testimony which had "wholesale reversals of his testimony under oath" without any explanation); Stein v. Foamex Int'l, Inc., No. 00-2356, 2001 WL 936566, at *5 (E.D. Pa. Aug. 15, 2001) (excluding expert affidavit where expert never claimed to have played any substantial role in its preparation, other than signing it, and party offered no evidence that expert prepared affidavit in any meaningful way).

- 12 The DPPs argue that Dr. Westreich has reviewed internal Reckitt documents, including the survey of how 300 doctors reacted to Reckitt's promotional statements, and as such, he is qualified to render opinions about physicians in general. I disagree. Dr. Westreich is a physician, not a statistician who has conducted extensive surveys about which he can testify.
- 13 Defendant also argues that Dr. Westreich's report is undermined by his own deposition testimony where he states that when teaching medical students or young doctors how to evaluate claims that drug manufacturers make about their products, he tells them to rely on research that has a solid scientific basis as opposed to marketing materials from the drug companies unless there is substantiation. (Westreich Dep. 138:16–140:21.) Any such contradiction between Dr. Westreich's opinion as to prescribing practices in his experience and Dr. Westreich's deposition testimony regarding such practices is not the basis for exclusion of his report, but rather is properly raised on cross-examination.
- 14 (See, e.g., Westreich Rep. ¶ 103 ("Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry."); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 ("From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis."); ¶ 155 ("documents extrinsic to the paper also show that it was finalized under extraordinary time pressures, which may also have contributed to data inaccuracies."); ¶ 189 ("as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse and Diversion study.").)
- 15 Mr. Verscharen succinctly explained the difference between AB-rated substitution and therapeutic substitution. When a prescription has an AB-rated generic, the pharmacist has the authority, and in most states, the responsibility, to use a generic whenever available. If no AB-rated generic is available, then the pharmacist must fill the prescription as written.

In some limited instances, however, a pharmacist may attempt to do a therapeutic substitution. This may occur when a pharmacist receives a prescription for a brand name drug that does not have an AB-rated generic associated with it, but there may be another drug available with a similar therapeutic result that might provide benefits (economic or clinical) to the patient, as well as economic benefits to the pharmacy. This other drug would have a different chemical, dosage strength or dosage form, and would be dispensed in place of the originally prescribed product. For therapeutic substitution to occur, however, the pharmacist must call the doctor and have the prescription changed. (Verscharen Rep. ¶¶ 48–50.)
- 16 Defendant also challenges Zettler's third and fourth opinions above, but raises them in the context of its "Motion to Exclude Plaintiffs' Expert Opinions Asserting or Relying Upon Assertions that Alleged Reckitt Safety Messages Were 'False,' 'Misleading,' 'Disparaging,' 'Fabricated,' 'Fraudulent,' 'Sham,' or 'Deceptive.'" I discuss these arguments *infra*.
- 17 During her deposition, Professor Zettler expanded on her FDA experience. (Zettler Dep. 38:15–40:19.) With respect specifically to shared REMS programs, Professor Zettler noted that she "provided legal advice on any issues that came up with those particular REMS...[and on] whatever legal issues might have come up for the agency" and specifically

identified two REMS that she worked on with elements of shared safe use and single shared systems. (*Id.* at 60:3–61:12.) To the extent Defendant argues that Professor Zettler did not work on a waiver request while at the FDA, the DPPs accurately note that the SSRS waiver in this case was the first ever granted and it occurred just months before she left the FDA in 2013. (*Id.* at 273:6–274:11.) Nonetheless, based on her experience, she was able to discuss the waiver statute and its requirements. (*Id.* at 274:4–278:20, 284:6–286:22.)

- 18 Defendant cites to several cases for the proposition that the meaning of federal regulations is not a question of fact on which experts may opine, but rather a question of law to be resolved by the court. These cases are distinguishable. In [Bammerline v. Navister International Transportation Corp.](#), 30 F.3d 898 (7th Cir. 1994), for example, a driver brought an action against a truck manufacturer for injuries sustained in an accident, alleging that the manufacturer designed the seat belt assembly improperly. *Id.* at 900. Given that the ultimate issue in the case involved whether the seat belt assembly was defective, the court found that an expert's testimony that the seat belt assembly did not comply with Federal Motor Vehicle Safety Standards impermissibly usurped the role of the jury. *Id.* Similarly, [Gordon v. New England Central Railroad, Inc.](#), No. 17-154, 2019 4068639 (D. Vt. Aug. 28, 2019) involved a negligence claim against a railroad for failure to appropriately maintain track facilities. The court found that an expert report which was to “determine the standard of care” under federal regulations was an improper legal conclusion because “standard of care” is a legal decision within the province of the court. *Id.* at *3. It further found that expert's opinion that the violation of federal regulations caused the collapse of the embankment was an ultimate conclusion exclusively within the province of the jury. *Id.*
- 19 Defendant asserts numerous challenges to this letter, arguing that (a) it does not state that the safety claims were false; (2) to the extent it can be read to state that film did not possess any safety benefits, “the letter would be expressing an inadmissible opinion with no foundation”; and (3) the passages relied upon by Plaintiffs are inadmissible hearsay. These arguments are not appropriate for resolution in this [Daubert](#) motion.
- 20 Defendants cite two cases for this proposition, neither of which are applicable here. See [Meadows v. Anchor Longwall and Rebuild](#), 306 F. App'x 781, 790 (3d Cir. 2009) (excluding expert where testimony did not fit with the otherwise uncontroverted evidence before the court); [Brugler v. Unum Grp.](#), No. 15-1031, 2019 WL 4452226, at *15 (M.D. Pa. Sept. 17, 2019) (excluding expert testimony where it was based on mere assumptions without any factual founding, thus rendering testimony unreliable).

2015 WL 8334544

United States District Court, M.D. Pennsylvania.

Candy S. ORNER, Plaintiff,

v.

NATIONAL BEEF PACKAGING COMPANY, LLC, Defendant.

No. 4:13-cv-0837

I

Signed 12/09/2015

Attorneys and Law Firms

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MEMORANDUM

Matthew W. Brann, United States District Judge

*1 In consideration of the parties' briefing, this case's procedural history, and the Daubert hearing before the Court, Defendant's Motion to Strike is granted in part and denied in part in accordance with this Memorandum. Specifically, Daniel M. Rappucci's methodology is sufficiently reliable under Daubert and Paoli II, but his testimony will be subject to thorough cross-examination and is limited as set forth herein. In addition, neither Mr. Rappucci nor any other expert may offer legal conclusions as to whether Defendant violated the ADA.

I. BACKGROUND

The particular facts of this case have been set out at length in Magistrate Judge Thomas M. Blewitt's October 8, 2014 Report and Recommendation granting part and denying in part Defendant's First Motion to Strike Mr. Rappucci's Expert Report¹ as well as Chief Magistrate Judge Martin C. Carlson's Report and Recommendation denying Plaintiff's Motion for Summary Judgment.² Nevertheless, the pertinent facets of this case's history are reiterated here.

Plaintiff began working as a "tray packer" at Defendant's Hummel's Wharf beef packaging facility in 2005.³ As a tray packer, Plaintiff worked side-by-side other beef packers on a production line, standing and facing long metal tables that contained a work area and a beef conveyor belt.⁴ Tray packers like Plaintiff reach and grab Styrofoam meat trays from above the packing lines and arrange cuts of meat on the trays as the meat moves along the conveyor belt.⁵ The finished product of a tray packer resembles a package of various meat cuts that a consumer might purchase at a supermarket from the butcher's shelf.

Beginning in 2005 and continuing through 2011, Plaintiff began to suffer back pain that affected her ability to perform the essential functions of her tray-packing job.⁶ Plaintiff has a history of back problems, including degenerative disc disease, for which she took certain prescription medication and received physical therapy during her employment with Defendant.⁷ Ultimately, Plaintiff would end up missing several weeks of work beginning in late 2011 due to back surgery.⁸

Plaintiff claims that Defendant repeatedly denied her requests for a reasonable accommodation pursuant to the Americans with Disabilities Act that would have allowed her to return work after her 2011 surgery.⁹ Though Plaintiff attempted to return to work in February 2012 with the aid of certain doctors' notes, those attempts proved unsuccessful.¹⁰ Specifically, the record reveals certain misgivings on Defendant's part as to whether Plaintiff could effectively perform her meat tray-packer role from a seated position.¹¹ Plaintiff and Defendant accordingly dispute the extent to which Plaintiff's not being able to return to work constituted a violation of the ADA in the form of a failure to accommodate claim. To that end, on March 23, 2015, this Court adopted in full Chief Magistrate Judge Carlson's Report and Recommendation denying Defendant's Motion for Summary Judgment.¹² Jury selection and trial is set to begin on February 22, 2016.¹³

*2 As it relates to the present issue, this is not the first time that Defendant has contested Mr. Rappucci's admissibility as an expert. In fact, this is effectively Defendant's second bite at the apple of exclusion. On May 30, 2014, Defendant filed a Motion to Strike certain exhibits on which Plaintiff had relied on in her opposition to Defendant's Motion for Summary Judgment.¹⁴ One of those exhibits was the presently contested expert report of Mr. Rappucci.¹⁵ According to Defendant, Mr. Rappucci's report should have been excluded under [Fed. R. Evid. 702](#) because it was "unreliable, unhelpful and assert[ed] legal conclusions."¹⁶ This Court largely disagreed, adopting in full Magistrate Judge Blewitt's Report and Recommendation, which granted in part and denied in part Defendant's Motion to Strike.¹⁷ In its Order, this Court explained:

To the extent that Plaintiff's expert Rappucci's Report offers opinions on legal issues, they are excluded.
The remainder of Rappucci's Report and the report of Plaintiff's expert Dr. Glass are not excluded.¹⁸

That particular language was included in the Order to clarify Magistrate Judge Blewitt's recommended disposition. Magistrate Judge Blewitt wrote:

As discussed above, we agree with Plaintiff that Rappucci's testimony is reliable and very relevant in this case. We find that Rappucci should be allowed to testify about the stated issues and render his mentioned opinions in this case. We find that his testimony is relevant to the jury's determination in this case with respect to Plaintiff's ADA claim against Defendant, and that it will aid the jury in resolving the factual disputes in this case. However, as discussed, to the extent Rappucci states an opinion as to whether Defendant has complied with the law, we find that Rappucci's testimony should be excluded.¹⁹

Defendant now brings what is essentially a renewed Motion to Strike Mr. Rappucci's same report. In all fairness to Defendant, what at least in part has prompted this subsequent challenge to Mr. Rappucci's reliability were statements made by him during his July 9, 2015 deposition.²⁰

Although Plaintiff correctly notes that Mr. Rappucci's underlying report and methodology has not changed since the first Motion to Strike, certain portions of the July 2015 deposition, both as reiterated by Veronica Winter Saltz, Esquire, counsel for the defense, during a status conference with this Court and as gathered by the Court during its own independent review of the deposition testimony, were, to put it plainly, less than confidence-inspiring. While the Court well understands the stresses associated with giving (or taking) deposition testimony, certain of the shortcomings evident during Mr. Rappucci's deposition—

particularly those involving uncertainty as to measurements and the lack of meaningful vocational testing—are likely to hinder his credibility with a jury in a reasonable accommodations case.

Still, as explained more fully below, the framing of the instant Motion during the Court's Daubert hearing was functionally more akin to a motion in limine than a motion to strike Mr. Rappucci's analysis in full. This posture was further facilitated by the fact that Mr. Rappucci's report can be demarcated into five distinct issues: (i) reasonable accommodation; (ii) direct threat to self; (iii) direct threat to others; (iv) undue hardship; and (v) qualified individual with a disability status. Moreover, given the existence of the preceding Order adopting in full Magistrate Judge Blewitt's Report and Recommendation, the Court and the parties have deemed it necessary to more fully flesh out the bounds of Mr. Rappucci's testimony so that the parties' expectations about trial are as settled as possible.

***3** Defendant primarily contends that Mr. Rappucci's methodology lacked the kind of thoroughness otherwise required to ensure reliability and subsequent testing. According to Defendant:

By his own admission, Rappucci relied on no measurements, applied no methodology, conducted no testing, performed no job analysis, requested no functional capacity evaluation, did not consider if Orner could perform the essential functions of her job with his suggested accommodation, performed no risk analysis as to safety relating to Orner and National Beef's employees and did not even purchase the suggested accommodation—a sit-stand stool. All Rappucci did in formulating his opinions/conclusions was to conduct a one-time vocational clinical interview of Orner, visit National Beef's plant and perform an internet search to find two “examples” of a sit-stand stool. By his own admission, his only concern was whether a sit-stand stool could physically be placed on the assembly line.²¹

Plaintiff, however, describes Defendant's efforts on this second Motion to Strike as follows:

All Defendant offers beyond what they argued in their previous attempt to strike Rappucci as an expert is take snippets of Rappucci's deposition and place them before the Court in a way that is either (1) misleading and out of context or (2) a simple reiteration of Rappucci's report which has already been ruled upon favorably by the Court.²²

Plaintiff contends that Defendant mischaracterizes Mr. Rappucci's methodology, stating that in fact his review of the facts was much more extensive:

Rappucci's report details in Appendix A both the factual record as well as the technical resources relied upon by Rappucci to formulate his report and opinions. In addition to an onsite visit on August 29, 2013, in which Rappucci observed the job duties of a Tray Packer and the design of the Tray Packer line to assess potential reasonable accommodations for Ms. Orner, Rappucci interviewed Ms. Orner on July 2, 2013. Rappucci also reviewed National Beef records, the depositions of all National Beef employees, the pleadings in the case, National Beef's responses to Plaintiff's Interrogatories and Ms. Orner's voluminous medical records. Rappucci referred to photographs taken during his onsite visit at National Beef as

well as technical resources available, including the EEOC's Technical Assistance Manual and the Job Accommodation Network.²³

The contested reasonable accommodation that emerged from Mr. Rappucci's analysis was a "sit-stand stool," a device resembling a stool with a back support that would purportedly permit Plaintiff to remain standing in a seated position at her spot in the meat packing line.²⁴ At his deposition, Mr. Rappucci repeatedly indicated that although he did not note all possible measurements, he focused on the measurements that "were important" to him in determining whether a sit-stand stool could reasonably accommodate Plaintiff.²⁵ Specifically, Mr. Rappucci stated the following during his deposition:

I pretty much was on my own to observe the meat, how it came down the conveyor belts, observe how the individuals took it from the belts, packed it, put it back—trayed[sic] it, put it back on the belts. I observed where they worked, their workstation. I observed the number of people. I observed the amount of meat. I observed the area, took some pictures, took some measurements, and I was done.

*4 ...

I believe I took measurements of the height of the packing shelf to the floor, the distance under the—under the unit, you know, like say from the end of the packing shelf to where it kind of obstructed off.

...

I measured the—I looked at the lean into the tray—to the meat area. I measured the people back to back, how much distance was between the rows of the people. I measured—I'm trying to remember what my notes mean here hang on a second—the number of people on the lines, how many lines, the height of some of the trays that were stacked on the middle of that unit, if you know—you know, the clean trays that they reach up for, the edge of the packaging tray to the underside. I called it a slap or drip tray. There was a drip tray there eight-inch depth, the distance from one tray line to the other line, and I looked at the height of the unit, you know, the various—like the— where they package, the white—the white unit to the floor, the center line tray reach, as I said, reach to the high trays.

I measured things, you know, based on my finger to waist measurements in consideration of Candy being 5 foot 1 and I being 5 foot 6. I measured—well, I think I've given you pretty much everything.

I looked at the height to the trays, the height of the unit to the floor, the distance under the unit before obstruction, the distance between the units. You know, when I say "unit," I mean the whole tray packing line, distance between the two. That's about it, I guess. That's all I can figure out from these old notes.

Moreover, Plaintiff argues that even given the foregoing, the admissibility of Mr. Rappucci's testimony has already been established and that it would be improper for this Court to wholly renounce its prior Order under the law of the case doctrine, given what little has changed since that time.²⁶

II. LAW

Federal Rules of Evidence 702 and 703 govern the admissibility of expert testimony. They provide as follows:

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.²⁷

Rule 703. Bases of an Expert's Opinion Testimony

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.²⁸

*5 In 1993, the Supreme Court of the United States set out the standard for admissibility of expert testimony in federal court in Daubert v. Merrell Dow Pharm., Inc.²⁹ The Court in Daubert delegated to district courts a “gatekeeping responsibility” under Rule 702, which requires them to “determine at the outset” whether an expert witness can “testify to (1) scientific knowledge that (2) will assist the trier of fact.”³⁰ That gate-keeping function demands an assessment of “whether the reasoning or methodology underlying the testimony is scientifically valid” as well as “whether that reasoning or methodology properly can be applied to the facts in issue.”³¹ Daubert also clarified that the proponents of the expert must establish admissibility by a preponderance of the evidence.³²

Though it recognized that “many factors” are relevant to this inquiry and that “a definitive checklist or test” does not exist, the Daubert Court enumerated four relevant questions for district courts to consider when making the Rule 702 determination: (1) whether the disputed methodology is testable; (2) whether the disputed methodology has been peer-reviewed; (3) the methodology's known or potential rate of error; and (4) whether the methodology is generally accepted in the relevant scientific community.³³

Daubert explained that district courts should conduct this inquiry in addition to that already mandated by Federal Rules of Evidence 703, which governs admission of expert testimony using data reasonably relied upon by experts in a particular field, and Federal Rule of Evidence 403, which permits exclusion of relevant evidence whose “probative value is substantially outweighed by a danger of...unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”³⁴ A district court “exercises more control over experts than over lay witnesses,” the Supreme Court observed, since “[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.”³⁵ Six years later, in Kumho Tire Co. v. Carmichael, the Supreme Court extended Daubert's holding as well as the district court's gate-keeping role beyond scientific expert testimony to all expert testimony based on “technical” or “other specialized knowledge.”³⁶

In 1994, the United States Court of Appeals for the Third Circuit issued its interpretation of Daubert in In re Paoli R.R. Yard PCB Litig., a decision known as Paoli II.³⁷ Paoli II cast the expert admissibility determination in light of three requirements: (1) qualification; (2) reliability; and (3) fit.³⁸ The qualification prong demands that the proffered expert possess sufficient “specialized knowledge” to testify as an expert.³⁹ The Third Circuit has interpreted this requirement broadly.⁴⁰ In this Court's view, the requirement that does the most work is naturally that of reliability. To satisfy the reliability prong, an expert's opinion “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’”⁴¹

Paoli II set forth an additional four factors to those provided in Daubert. That list of factors, which “a district court should take into account,” reads as follows:

*6 (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.⁴²

With regard to the third prong, fit, the Paoli II Court explained that admissibility “depends...on ‘the proffered connection between the scientific research or test result...and [the] particular disputed factual issues.’”⁴³ In recognition then of Paoli II's interpretation of Daubert, Third Circuit courts confronting expert witness issues have recognized that admissibility requires a proffered expert to surpass “a trilogy of restrictions”: qualification, reliability and fit.⁴⁴

“Determinations regarding the weight to be accorded, and the sufficiency of, the evidence relied upon by the proffered expert, are within the sole province of the jury.”⁴⁵ Thus, Rule 702 has been said to embrace “a liberal policy of admissibility.”⁴⁶

III. ANALYSIS

A. Neither Mr. Rappucci Nor Any Other Expert May Offer Legal

Conclusions As To Whether National Beef Violated The ADA. The parties to this dispute have stumbled upon a schizophrenic area of the law, an evidentiary dispute unamenable to bright line rules and more intricate than is first apparent. Specifically, Federal Rule of Evidence 704(a), the provision regulating expert testimony on an ultimate issue, deceptively states that “[a]n opinion is not objectionable just because it embraces an ultimate issue.” That seemingly clear expression favoring (or at least not disfavoring) admissibility belies an extensive body of case law that has applied a more discerning approach to expert opinions that go to an ultimate issue.

As the Third Circuit stated in Berkeley Inv. Grp., Ltd. v. Colkitt, a leading decision on the subject, “an expert witness is prohibited from rendering a legal opinion.”⁴⁷ Several circuit courts have adopted this stringent view and have offered several justifications for this outright bar on legal opinions by expert witnesses.⁴⁸ For example, the Third Circuit has explained that a restrictive approach to expert opinions on an ultimate issue guards against an expert “usurp[ing] the District Court's pivotal role in explaining the law to the jury,”⁴⁹ prevents a witness from “invad[ing] the province of the jury,”⁵⁰ and avoids a party's “attempting to introduce law as evidence.”⁵¹

*7 Though the Advisory Committee Notes to Federal Rule 704 indicate a preference for a “helpful[ness] to the trier of fact” standard over a stringent “ultimate issue rule,” such preference has provided little guidance for federal courts. As those Advisory Committee Notes state, “[A]bolition of the ultimate issue rule does not lower the bars so as to admit all opinions. Under Rules 701 and 702, opinions must be helpful to the trier of fact, and Rule 403 provides for exclusion of evidence which wastes time.” Thus, taken together, Rules 403, 701, 702, and 704 “stand ready to exclude opinions phrased in terms of inadequately explored legal criteria.”⁵²

In attempting to clarify when an expert runs afoul of the Federal Rules of Evidence when offering ultimate opinions, the Advisory Committee Notes to Rule 704 offer the following helpful example:

Thus the question, “Did T have capacity to make a will?” would be excluded, while the question, “Did T have sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution?” would be allowed.

Interpreting this example, the United States Court of Appeals for the Tenth Circuit has stated that a trial court's primary inquiry is “distinguishing between testimony on issues of law and testimony on ultimate facts,” where “testimony on the ultimate factual questions aids the jury in reaching a verdict; testimony which articulates and applies the relevant law, however, circumvents the jury's decision-making function by telling it how to decide the case.”⁵³ According to the Tenth Circuit, district courts should thus exclude testimony that “simply tell[s] the jury to reach a particular verdict based on [the expert's] own say-so.”⁵⁴ Similarly, the United States Court of Appeals for the Sixth Circuit has explained that expert testimony as to an ultimate issue is inappropriate when “the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.”⁵⁵ In like manner, the United States Court of Appeals for the District of Columbia Circuit illustrated the distinction between “impermissible legal conclusions” and “permissible factual opinions” with the following example: “[A]n expert may offer his opinion as to facts that, if found, would support a conclusion that the legal standard at issue was satisfied, but he may not testify as to whether the legal standard has been satisfied.”⁵⁶

This distinction becomes particularly hazy, however, in cases such as this one, which involve statutory schemes, legal terms of art, and specialized practices that fall well beyond the scope of lay person's common knowledge. As the Third Circuit stated in Berkeley, “the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties.”⁵⁷ The paradox is apparent: jurors in ADA cases require a certain contextualization of the applicable law and the vocational practices the ADA has spawned, yet the ultimate determination as to liability must remain the jury's and the jury's alone.

*8 Yet, this Court believes that Berkeley and the cases upon which Berkeley relies provide a helpful framework for the parties here and therefore are also an appropriate starting point for the instant discussion. Berkeley involved expert testimony offered to controvert alleged violations of the federal securities laws.⁵⁸ As a starting point, the Third Circuit recognized in Berkeley that although previous cases considered it permissible for an expert “to testify as to the established custom in [a given] industry,” it was not appropriate for the expert “to give his opinion as to the legal duties arising from the industry custom.”⁵⁹ Similarly, the Berkeley court emphasized that the “[k]ey to our determination” in previous cases “was that the expert did not give his opinion as to what was required under the law, or whether the defendant complied with the Act.”⁶⁰ Instead, where such testimony was permissible, the expert testified as to business custom “based upon his experience in the [] industry.”⁶¹

Addressing the contested expert testimony in Berkeley, the Third Circuit observed that the witness's “background testimony could be helpful to the jury.”⁶² The witness was “an experienced former counsel for the SEC with expertise in offshore securities transactions.”⁶³ Testimony as to “[t]he customs and business practices in the securities industry” at the relevant time “provides an important context which will aid the jury” in making its ultimate determination.⁶⁴ Thus, although testimony as to business custom in light of given legislation was admissible, it would not be admissible for that expert to testify “as to whether [a party] complied with legal duties that arose under the federal securities laws.”⁶⁵ This prohibition extended to testimony regarding “the legal effect of the various SEC pronouncements” as well as to whether it was reasonable for a party to believe that it was entitled to a securities law exemption.⁶⁶

In the context of ADA litigation, several federal courts have applied Federal Rule of Evidence 704 to exclude expert testimony offering direct legal conclusions about such ultimate issues as whether a plaintiff “was disabled or impaired”⁶⁷ and whether a defendant “failed to engage in a meaningful interactive process;”⁶⁸ “engaged in discriminatory practices with reckless

indifference,”⁶⁹ or provided “a reasonable accommodation.”⁷⁰ As this Court indicated during its October 19, 2015 Daubert hearing, it is similarly prepared to exclude such legal conclusions in this case. Therefore, as applied to each of the specific ADA opinions that follow in the subsequent sections of this discussion, Mr. Rappucci (as well as any other expert offered by either party) may testify to those facts that bear upon the ultimate issue but may not state any blunt legal conclusion as to whether National Beef violated any portion of the ADA.

This means that expert witnesses in this case may not testify to any of the following issues in the form of direct legal conclusions: (i) whether Ms. Orner was “a qualified individual with a disability;” (ii) whether National Beef failed to “adequately engage in the interactive process;” (iii) whether the proposed sit-stand stool was a “reasonable accommodation;” (iv) whether implementation of the sit-stand stool would pose a “direct threat” to Ms. Orner or others; or (v) whether the sit-stand stool would not pose an “undue hardship” to National Beef.

*9 However, this prohibition does not mean that expert testimony that goes to any of those issues is per se inadmissible. To the contrary, this Court expects that factual testimony, which is based upon the experts' experience, research, and review of the record and which helps the jury reach its own legal conclusion as to each of these core ADA issues, will comprise the majority of the substantive testimony at trial. Thus, for example, the experts will be able to generally discuss the standard business practices typically implemented to facilitate the interactive process through which employees can make ADA requests; the leading treatises and related EEOC guidance upon which employers and experts generally rely; and typical considerations that experts and employers use to determine whether a requested accommodation is reasonable or would pose a direct threat in a given workplace. The experts, based upon their own research and investigation, may, for example, factually describe the sort of interactive process implemented at National Beef and discuss the particular factual considerations that indicate whether the sit-stand stool was reasonable or would pose a direct threat.⁷¹ The experts' testimony must stop, however, before reaching either of the following general topics: (i) the particular legal duties that the ADA imposes upon employers or (ii) whether National Beef complied with those duties in this case. The former topic is solely the responsibility of this Court; the latter determination is for the jury to decide. This Court also respectfully reminds both parties that it will look unfavorably upon any attempt to circumvent this or any other pretrial ruling during the course of trial.

B. Mr. Rappucci's Methodology Is Sufficiently Reliable Under Daubert And Paoli II, But His Testimony Will Be Subject To Thorough Cross-Examination And Is Limited As Follows.

Based on the Court's review of the case law dealing with vocational rehabilitation experts as well as the particular methodology undertaken by Mr. Rappucci, the Court concludes that Mr. Rappucci's work is sufficiently reliable under Rule 702 to warrant admissibility. As detailed more fully below, Defendant will enjoy wide latitude in cross-examining Mr. Rappucci on certain issues (whether the sit-stand stool was a “reasonable accommodation;” whether Plaintiff was a statutory “qualified individual” with that accommodation; and whether it posed a “direct threat” to others). In addition to the bar on legal conclusions set forth above in Part III.A, Mr. Rappucci will not be able to testify as to whether Plaintiff had a “disability” under the ADA or whether the proposed accommodation posed a “direct threat” to Plaintiff herself. Those latter two areas are more appropriately the province of Plaintiff's medical expert, Dr. Glass.

Defendant principally relies on two cases, Elcock v. Kmart Corp.⁷² and Oddi v. Ford Motor Co.⁷³ Elcock involved the exclusion of a proffered vocational rehabilitation expert intended to testify as to the lost earnings capacity of a plaintiff in a slip-and-fall torts suit.⁷⁴ There are significant differences between the instant case and Elcock. First, the contested expert in Elcock, unlike Mr. Rappucci here, “admitted that he had neither the academic training nor the standard credentials that would ordinarily qualify one as an expert in vocational rehabilitation.”⁷⁵ The Elcock court noted that “this marginal nature of [the witness's] qualifications” necessarily “enter[s] into the Daubert calculus.”⁷⁶ To the contrary, Mr. Rappucci has over forty years of experience in the vocational rehabilitation arena.⁷⁷

Moreover, as far as the legitimacy of the chosen methodology goes, the excluded expert in Elcock offered “an idiosyncratic or subjective judgment in which the result can neither be duplicated nor tested for validity”—a broken (or non-existent) methodology that involved random changes in estimates and was largely “untested,” “novel,” and “arbitrary.”⁷⁸ Not so here. Mr. Rappucci reviewed two pertinent ADA treatises, met with Plaintiff, obtained estimates of her physical tolerances, visited Defendant's facility, measured the work area, observed the environment where Plaintiff would perform her job, and researched potential sit-stand stools that he felt would satisfy her needs without posing a hazard to others. The Court finds that to be a sufficiently reliable methodology because, importantly, it can be replicated, tested, verified, or debunked by Defendant's own experts.

***10** Similarly, Oddi v. Ford Motor Co involved the exclusion of an engineer who was retained to testify about the alleged defective design in the bumper of a Ford truck that was involved in a catastrophic accident.⁷⁹ The expert in Oddi testified that the truck involved in the collision was defectively designed, but “was unable to identify any particular literature that he relied upon to form any of the opinions contained in his preliminary report.”⁸⁰ Mr. Rappucci's work, however, is not so untethered from scholarly literature in the form of EEOC guidance on implementation of the ADA. Moreover, the expert in Oddi failed to make several key findings related to the force of the accident, the capacity of the bumper, etc.⁸¹ Certain of his findings were even openly “undermined by the [] laws of physics.”⁸² Even if imperfect, Mr. Rappucci relied upon sufficient measurements and observations in forming his opinions to at least allow his work to surpass Daubert's requirements.

This Court believes that Mr. Rappucci's admission as an expert is consistent with several other federal decisions on this topic. For instance, in Hamilton v. Emerson Elec. Co., the Honorable James F. McClure, Jr., writing for this Court, found it proper to exclude an expert who, unlike Mr. Rappucci, “did not...do any analysis,” “did not do any independent examination or evaluation,” and “[did] not use any discernible methodology.”⁸³ The same is true when comparing Mr. Rappucci's methodology in this case to that at issue in a decision by the United States Court of Appeals for the Seventh Circuit that resulted in exclusion of an expert whose testimony “[was] not based on any specific methodology applied to the facts but [was] only unsupported speculation.”⁸⁴

As the Elcock court explained, “[v]ocational rehabilitation is a social science that does not exactly mirror the fundamental precepts of the so-called harder sciences. However, the gist of the above Daubert factors are nonetheless implicated.”⁸⁵ The precise issue here as highlighted by the Court's Daubert hearing, is the minimum threshold of testing, measurement, and analysis required of a vocational rehabilitation analyst before he may be admitted as an expert. Does the analyst need to actually test the accommodation out with the subject of the litigation? And for how long? Plaintiff cites to Weirich v. Horst Realty Co., LLC, which explained that “[d]espite Defendant's implication, vocational experts, like medical and other experts, 'are not required to review every record or perform every conceivable test' in order to reach a reliable conclusion that has proper factual support.”⁸⁶

The reality is that prolonged testing mimicking actual performance of one's everyday duties, is simply not a feasible option at times. That does not mean that it is never warranted or that there is not a minimum level of demonstration that would aid a party's admissibility efforts as well as its chances of success on the underlying merits. That being said, given the nature of a vocational rehabilitation analyst's work, it is reasonable for a certain amount of research, investigation, and consultation with the injured individual to substitute for a thorough nine to five demonstration under real-time workplace conditions. That line will often be a fact-dependent one, and based upon the facts and procedural history of this case, the Court is satisfied that Mr. Rappucci's methodology has met that minimum threshold.⁸⁷

***11** The parties are reminded, however, that the Court's preceding discussion here is limited solely to the threshold issue of admissibility and is not meant to any way bear upon Mr. Rappucci's potential credibility. As evidenced by certain of the issues that the parties analyzed during the Court's Daubert hearing, the threshold admissibility determination here was not an easy one, particularly as it relates to the issues of reasonable accommodation and direct threat. Whereas certain experts effortlessly clear

the hurdle of admissibility, based on this Court's review of the pertinent reports and deposition testimony, Mr. Rappucci might graciously be described as having grazed that hurdle on his way over, leaving it wobbling as he passed by.

Nevertheless, this Court believes that the apparent shortcomings in Mr. Rappucci's report and testimony are better addressed through vigorous cross-examination than through threshold exclusion, as they go primarily to the credibility, completeness, and thoroughness of his recommendations rather than to the preliminary validity of a vocational rehabilitation expert's methodology.⁸⁸ As the Third Circuit has explained:

Courts have held in numerous other cases that credibility is irrelevant to determining whether a proposed expert witness's testimony is admissible under [Rule 702](#), and particularly whether it is based on reliable methodology. *See, e.g., Breidor v. Sears, Roebuck & Co.*, 722 F.2d 1134, 1138-39 (3d Cir.1983) (“Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.”)...Similarly, factual errors in a witness's testimony are not grounds for excluding the witness from testifying as an expert. *See Paoli II*, 35 F.3d at 753–54. Finally, general attacks on credibility based on a lack of personal knowledge are not a proper basis for excluding expert testimony. *See Dixon v. International Harvester Co.*, 754 F.2d 573, 580 (5th Cir.1985).⁸⁹

In the Court's view, then, admission here is largely proper, and a close cross-examination will permit Defendant to adequately vet Mr. Rappucci's recommendations for the jury's benefit, a vetting that is appropriate in light of certain of the alleged omissions in Mr. Rappucci's analysis. To that end, both parties should expect the Court to afford Defendant's counsel wide latitude on its cross-examination of Mr. Rappucci. I anticipate that little will be off limits, and Mr. Rappucci will be expected to testify fully to as to why he did not test Ms. Orner in any capacity;⁹⁰ why he relied primarily on tolerance estimates self-reported by Ms. Orner;⁹¹ why certain measurements were irrelevant to his analysis;⁹² and why he did not conduct a functional capacity evaluation (FCE) of Ms. Orner.⁹³

Such latitude will be especially wide in the likely event that Defendant's counsel wishes to question Mr. Rappucci about his determinations that the sit-stand stool is a reasonable accommodation that would not pose a direct threat to others, opinions that although admissible under [Rule 702](#), may raise serious logistical doubts in any reasonable juror's mind given the particular workplace setting at issue. This wide latitude will naturally extend to any discussion by Mr. Rappucci as to whether Plaintiff was a “qualified individual” under [42 U.S.C. § 12111\(8\)](#). Given that Mr. Rappucci's opinion of the sit-stand stool as a reasonable accommodation that does not pose a direct threat is arguably that most called into question by his alleged lack of thoroughness, the Court finds it fitting that Defendant's counsel be afforded significant leeway to question Mr. Rappucci on those particular conclusions in the presence of the jury. In that vein, the Court believes that how the jury receives Mr. Rappucci's testimony will play a significant role in whether they judge Ms. Orner's claim meritorious or unavailing.

***12** As compared to his analysis on reasonable accommodation and direct threat, the soundest portion of Mr. Rappucci's report is his analysis of the interactive process that played out between National Beef and Ms. Orner. Mr. Rappucci devotes five pages of his report to reviewing the pertinent manuals, analyzing deposition testimony and correspondence between the parties, and discussing the particulars associated with implementation of the sit-stand stool for Ms. Orner. In the Court's view, this particular portion of Mr. Rappucci's testimony will be quite helpful to the jury. This is especially true in light of Plaintiff's core contention that National Beef and its representatives did not adequately engage in the interactive process with Ms. Orner. Based on Mr. Rappucci's background and deposition testimony, his explanation of the interactive process and related concepts also seems to be the area in which he is most qualified and with which he has the most experience. As such, although he may not testify to any specific legal conclusions as explained in Part III.A above, Mr. Rappucci will be afforded the widest latitude as it pertains to his discussion of the interactive process.

Last, there are certain ADA issues about which this Court deems it improper for Mr. Rappucci to testify. Those two primary areas that are beyond the bounds of his expertise, as acknowledged by Plaintiff during the Court's [Daubert](#) hearing, are whether Plaintiff was “disabled” under the ADA as well as whether the sit-stand stool would pose a “direct threat” to Plaintiff. Both

of those issues are more appropriately addressed by Plaintiff's medical expert, neurologist Dr. Jon Glass, on direct and cross-examination. Mr. Rappucci's testimony, by virtue of his training as a vocational rehabilitation analyst, will thus be limited to the issues of reasonable accommodation, qualified individual status, and direct threat to others. Finally, the Court considers it improper for Mr. Rappucci to opine as to whether the sit-stand stool would pose an undue hardship for Defendant. He may testify as to the price of the device, but his analysis should end there.

IV. CONCLUSION

This is a dispute in which each party suggests that the other “stopped short” of what the ADA requires. According to Defendant, Plaintiff's expert Mr. Rappucci stopped short of fully investigating and analyzing what might constitute a reasonable accommodation. On the other hand, Plaintiff, through Mr. Rappucci, suggests that Defendant stopped short of fulfilling its obligations under the ADA by failing to adequately engage in the interactive process. As occasionally is the case in a dispute such as this, perhaps there is some truth to both positions.

In light of this consideration, the Court would encourage both parties to put serious thought into the best way to resolve the instant dispute. Although, as this Court has repeatedly indicated, it will be prepared to oversee a jury trial commencing two months from now, the litigants are now in a better position than they have ever been to evaluate the strengths and weaknesses of each side's case. Given these newly settled expectations about a February 2016 trial, the parties may decide that coming to a cooperative resolution in a case like this is a far preferable option to punting that determination to a jury of eight laypeople unschooled in the ADA, a delegation that could have undesired consequences for either party if it is true that both have indeed “stopped short.”

An appropriate Order follows.

All Citations

Not Reported in Fed. Supp., 2015 WL 8334544, 99 Fed. R. Evid. Serv. 109, 2015 A.D. Cases 404,044

Footnotes

1 ECF No. 55.

2 ECF No. 60.

3 Id. at 4. Hummel's Wharf is a “census-designated place” (CDP) in Snyder County, Pennsylvania.

4 Id.

5 Id.

6 Id.

7 Id.

8 Id. at 5.

9 Id. at 1–2 (citing 42 U.S.C. § 12101 et seq.).

- 10 ECF No. 60 at 5.
- 11 Id.
- 12 ECF No. 61.
- 13 ECF No. 74 at 1.
- 14 ECF Nos. 44, 45 at 1.
- 15 ECF No. 45 at 2.
- 16 Id.
- 17 ECF No. 58.
- 18 Id. at 2.
- 19 ECF No. 55 at 17.
- 20 ECF No. 77 Ex. 2.
- 21 ECF No. 77 at 2–3.
- 22 ECF No. 82 at 11.
- 23 ECF No. 82 at 10.
- 24 Photos and attendant descriptions of potential sit-stand stools are available in Mr. Rappucci's report. ECF No. 77 Ex. 1 at 15–16.
- 25 ECF No. 77 Ex. 2 at 11.
- 26 ECF No. 82 at 2–5.
- 27 Fed. R. Evid. 702.
- 28 Fed. R. Evid. 703.
- 29 509 U.S. 579 (1993).
- 30 Daubert, 509 U.S. at 592.
- 31 Daubert, 509 U.S. at 592–93.
- 32 Daubert, 509 U.S. at 592 n.10 (citing Bourjaily v. United States, 483 U.S. 171, 175–76 (1987)). See also In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994) (Becker, J.) (“This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.”).
- 33 Daubert, 509 U.S. at 593–94.
- 34 Fed. R. Evid. 403.

- 35 Daubert, 509 U.S. at 595 (quoting Hon. Jack B. Weinstein, Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)).
- 36 526 U.S. 137 (1999)
- 37 35 F.3d 717, 730 (3d Cir. 1994).
- 38 Id. at 741–43.
- 39 Id. at 741.
- 40 See id.
- 41 See id. at 742 (quoting Daubert, 509 U.S. at 589).
- 42 See Paoli II, 35 F.3d at 742 n.8.
- 43 See id. at 743 (quoting United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985)).
- 44 See Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003).
- 45 Walker v. Gordon, 46 F. App'x 691, 695 (3d Cir. 2002).
- 46 Paoli II, 35 F.3d at 741.
- 47 455 F.3d 195, 217 (3d Cir. 2006).
- 48 See, e.g., Specht v. Jensen, 853 F.2d 805 (10th Cir. 1988); Marx & Co. v. Diners' Club, Inc., 550 F.2d 505 (2d Cir. 1977); Adalman v. Baker, Watts & Co., 807 F.2d 359 (4th Cir.1986); Owen v. Kerr–McGee Corp., 698 F.2d 236 (5th Cir.1983); United States v. Zipkin, 729 F.2d 384 (6th Cir.1984).
- 49 Berkeley, 455 F.3d at 217.
- 50 United States v. Downing, 753 F.2d 1224, 1229 (3d Cir. 1985).
- 51 United States v. Leo, 941 F.2d 181, 197 (3d Cir. 1991).
- 52 Fed. R. Evid. 704, Adv. Comm. Notes.
- 53 Specht v. Jensen, 853 F.2d 805, 808 (10th Cir. 1988).
- 54 United States v. Dazey, 403 F.3d 1147, 1171 (10th Cir. 2005).
- 55 Torres v. Cty. of Oakland, 758 F.2d 147, 151 (6th Cir. 1985).
- 56 Burkhart v. Washington Metro. Area Transit Auth., 112 F.3d 1207, 1212–13 (D.C. Cir. 1997).
- 57 455 F.3d at 218.
- 58 Id.
- 59 Id. (citing First Nat. State Bank of New Jersey v. Reliance Elec. Co., 668 F.2d 725 (3d Cir. 1981) (analyzing expert testimony that went to the “holder in due course” provision of the Uniform Commercial Code)).

60 Berkeley, 455 F.3d at 218 (citing Leo, 941 F.2d at 196–97 (analyzing expert testimony that went to the Armed Services Procurement Act)).

61 Berkeley, 455 F.3d at 218 (quoting Leo, 941 F.2d at 197).

62 Berkeley, 455 F.3d at 218.

63 Id.

64 Id.

65 Id.

66 Id.

67 Candlehouse, Inc. v. Town of Vestal, N.Y., No. 3:11-CV-0093 DEP, 2013 WL 1867114, at *22 (N.D.N.Y. May 3, 2013).

68 James Vaughn v. Safeway, Inc., No. 14-CV-01066-REB-NYW, 2015 WL 7307936, at *3 (D. Colo. Nov. 20, 2015).

69 Id.

70 Donelson v. Providence Health & Servs.-Washington, 823 F. Supp. 2d 1179, 1193 (E.D. Wash. 2011).

71 Further explanation is afforded to each of these particular ADA opinions in the subsequent sections, given that the Court has found the majority of Mr. Rappucci's methodology and testimony sufficiently reliable for the purposes of admission in federal court under Daubert and Paoli II.

72 233 F.3d 734 (3d Cir. 2000).

73 234 F.3d 136 (3d Cir. 2000).

74 233 F.3d at 740.

75 Id. at 741.

76 233 F.3d at 744.

77 ECF No. 77 Ex. 1 at 23.

78 233 F.3d at 746–48.

79 234 F.3d 136.

80 Id. at 148.

81 See id. at 149.

82 See id. at 157.

83 133 F.Supp.2d 360, 367–71 (M.D. Pa. 2001).

84 Ammons v. Aramark Unif. Servs., Inc., 368 F.3d 809, 815 (7th Cir. 2004).

85 Elcock, 233 F.3d at 747.

86 No. CIV. A. 07-CV-871, 2009 WL 920960, at *5 (E.D. Pa. Mar. 30, 2009).

- 87 A related question raised by counsel but not addressed during the Daubert hearing was the feasibility of an on-site visit to Defendant's facility. To best orient the parties' expectations, this Court would be unlikely to grant such a request and would instead be inclined to follow the analysis of the Honorable John A. Woodcock, Jr., in Rooney v. Sprague Energy Corp., 495 F. Supp. 2d 135, 138 (D. Me. 2007) (“The disadvantages of lost trial time, additional expense, and potential legal pitfalls substantially outweigh whatever slight incremental advantage, if any, an on-site visit would have over the presentation of alternative evidence.”).
- 88 The Court finds instructive comparison of the instant dispute to Bruno v. Bozzuto's, Inc., No. 3:09-CV-874, 2015 WL 7294464, at *15 (M.D. Pa. Nov. 19, 2015) (excluding experts whose methodological flaws “call[ed] into question the very corpus of the reports themselves” and therefore were unamenable to “to minor correction by the factfinder on the basis of some credibility determination”).
- 89 In re Unisys Sav. Plan Litig., 173 F.3d 145, 166 n.11 (3d Cir. 1999).
- 90 ECF No. 77 Ex. 2 at 6.
- 91 Id. at 7, 17.
- 92 Id. at 11–14.
- 93 Id. at 18.

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United States District Court, E.D. Pennsylvania.

UNITED STATES of America

v.

Gongda XUE, Defendant.

CRIMINAL ACTION NO. 18-122

|

Filed 04/06/2022

Synopsis

Background: Defendant, a citizen of China and a legal resident of Switzerland who was being held at federal detention center arising from allegations of involvement in conspiracy to steal trade secrets, filed emergency motion for temporary release from custody in view of the COVID-19 pandemic. The United States District Court for the Eastern District of Pennsylvania, [David R. Strawbridge](#), United States Magistrate Judge, granted the motion. The Government appealed. The United States District Court for the Eastern District of Pennsylvania, [Joel H. Slomsky](#), Senior District Judge, [459 F.Supp.3d 659](#), revoked order granting temporary release, and denied defendant's request for temporary release. The United States Court of Appeals for the Third Circuit, [Ambro](#), Circuit Judge, [2020 WL 6777547](#), vacated and remanded. On remand, defendant moved in limine to exclude at trial the testimony of government's proposed expert witnesses.

Holdings: The District Court held that:

[1] witnesses were qualified;

[2] proposed testimony was reliable;

[3] proposed testimony sufficiently fit facts of case;

[4] *Daubert* hearing was not necessary;

[5] as a matter of first impression, experts were precluded from using terms “secret” and “trade secret”;

[6] probative value in using phrase “trade secret” was outweighed by the danger of undue prejudice; and

[7] testimony that information at issue was confidential or proprietary, that information had economic value in biopharmaceutical industry, that steps were taken to preserve or keep confidential this information, and that used synonyms for the words “trade” and “secret” was not impermissible legal testimony.

Motion granted in part and denied in part.

Procedural Posture(s): Pre-Trial Hearing Motion.

West Headnotes (21)

[1] Criminal Law 🔑 Knowledge, Experience, and Skill

A broad range of knowledge, skills, and training qualify an expert. *Fed. R. Evid. 702*.

[2] Criminal Law 🔑 Knowledge, Experience, and Skill

It is an abuse of discretion to exclude expert testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate. *Fed. R. Evid. 702*.

[3] Criminal Law 🔑 Necessity and sufficiency

The evidentiary requirement of reliability for admission of expert testimony is lower than the merits standard of correctness. *Fed. R. Evid. 702*.

[4] Criminal Law 🔑 Necessity and sufficiency

Admissibility of expert testimony turns on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined. *Fed. R. Evid. 702*.

[5] Criminal Law 🔑 Necessity and sufficiency

When examining expert testimony that is based on practical experience, rather than academic theories, the *Daubert* factors such as peer review, publication, and potential error and rate are not applicable because the reliability of testimony from a practical experience expert depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it. *Fed. R. Evid. 702*.

[6] Criminal Law 🔑 Subjects of Expert Testimony**Criminal Law** 🔑 Aid to jury

To satisfy *Daubert's* “fit” requirement for admissibility of expert testimony, expert's testimony must be relevant for purposes of case and must assist trier of fact. *Fed. R. Evid. 702*.

[7] Criminal Law 🔑 Subjects of Expert Testimony

Under *Daubert*, expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. *Fed. R. Evid. 702*.

[8] Criminal Law 🔑 Matters Directly in Issue; Ultimate Issues

Although an expert witness is permitted to give expert testimony that embraces an ultimate issue to be decided by the trier of fact, an expert witness is prohibited from rendering a legal opinion. *Fed. R. Evid. 704*.

[9] **Criminal Law** 🔑 Matters Directly in Issue; Ultimate Issues

It is the role of the trial judge, not an expert witness, to explain the law to the jury. *Fed. R. Evid. 704*.

[10] **Criminal Law** 🔑 Knowledge, Experience, and Skill

Government's three proposed witnesses were qualified in the biopharmaceutical industry to offer expert testimony including whether certain information shared between defendant and other co-conspirators was confidential information or was information belonging to pharmaceutical company that was to be kept secret, in prosecution for conspiracy to sell trade secrets; witnesses had served as executives at biopharmaceutical companies, had over 30 years of experience in the industry, were educated on the subject matter in this case, held doctorate degrees in chemistry, biochemistry, and biomedical sciences, respectively, and had learned confidentiality practices at pharmaceutical companies. *Fed. R. Evid. 702*.

[11] **Criminal Law** 🔑 Sources of data

Proposed testimony of government's experts about proprietary information in biopharmaceutical industry and customs and practices for protecting information characterized as confidential, which was based on practical experience in biopharmaceutical industry, was reliable under *Daubert*, as would support admission in prosecution for conspiracy to steal trade secrets, even though proposed testimony was not based on testable theory or methodology subject to peer review; experts had been executives at biopharmaceutical companies, had several decades of experience in industry, were familiar with facts of case, would be able to testify reliably whether documents contained proprietary information, and would assist jury in understanding types of information that are kept confidential and what measures are taken to protect this information. *Fed. R. Evid. 702*.

[12] **Criminal Law** 🔑 Necessity and sufficiency

Daubert factors for determining whether to admit expert testimony are neither exhaustive nor applicable in every case. *Fed. R. Evid. 702*.

[13] **Criminal Law** 🔑 Miscellaneous matters

Proffered expert testimony of witnesses who were qualified as experts in biopharmaceutical industry would be helpful to the jury and assist their understanding of whether certain information was confidential and proprietary in the industry, or alternatively, was information that was widely available to the scientific community, and thus testimony sufficiently fit facts of case under *Daubert* to be admissible in prosecution for conspiracy to steal trade secrets from pharmaceutical company; experts' practical experience working as pharmaceutical executives provided a reliable basis for them to testify whether information shared between defendant and co-conspirators was confidential in industry, and arguments regarding fit went to weight of experts' testimony, rather than admissibility. *Fed. R. Evid. 702*.

[14] **Criminal Law** 🔑 Hearing, ruling, and objections

A court is not required to hold a *Daubert* hearing, even if it is requested, if the record allows the court to rule on admissibility. *Fed. R. Evid. 702*.

[15] **Criminal Law** 🔑 Hearing, ruling, and objections

Courts have discretion to grant or deny requests for a *Daubert* hearing. Fed. R. Evid. 702.

[16] **Criminal Law** 🔑 Hearing, ruling, and objections

An in limine hearing will not be required whenever a *Daubert* objection is raised to a proffer of expert evidence; whether to hold one rests in the sound discretion of the district court. Fed. R. Evid. 702.

[17] **Criminal Law** 🔑 Hearing, ruling, and objections

A *Daubert* hearing is not necessary where a court already has before it the depositions and affidavits of the proposed experts. Fed. R. Evid. 702.

[18] **Criminal Law** 🔑 Hearing, ruling, and objections

Evidence was sufficient regarding proposed expert testimony to allow court to rule on motion in limine to exclude experts' testimony, such that court was not required to hold a *Daubert* hearing in prosecution for conspiracy to steal trade secrets; experts' experience, qualifications, and expected testimony was known to court through previous testimony and extensive briefing regarding proposed testimony by defendant and government, experts were familiar with pertinent facts, and government had provided defendant in discovery four reports about documents at issue in case. Fed. R. Evid. 702.

[19] **Criminal Law** 🔑 Particular issues

Criminal Law 🔑 Miscellaneous matters

Use of terms “secret” or “trade secret” as understood in biopharmaceutical industry was impermissible as ultimate issue testimony and would have usurped district court's pivotal role in explaining the law to jury, and thus government's expert witnesses were precluded from using terms when testifying at trial in prosecution for conspiracy to steal trade secrets and receiving stolen trade secrets; one ultimate issue was whether alleged misappropriated information fell within statutory definition of “trade secret,” and jury was required to decide whether government proved beyond a reasonable doubt that documents in issue contained “trade secrets,” after carefully applying the facts they find to the law. 18 U.S.C.A. §§ 1832(a)(3), 1832(a)(5); Fed. R. Evid. 704.

[20] **Criminal Law** 🔑 Miscellaneous matters

Probative value in using phrase “trade secret” was outweighed by the danger of undue prejudice in the jury repeatedly hearing “trade secret” in government's proffered expert testimony, thus warranting exclusion of use of “trade secret” by government's experts in prosecution for conspiracy to steal trade secrets and receiving stolen trade secrets. 18 U.S.C.A. §§ 1832(a)(3), 1832(a)(5); Fed. R. Evid. 403.

[21] **Criminal Law** 🔑 Matters Directly in Issue; Ultimate Issues

Criminal Law 🔑 Miscellaneous matters

Testimony that information at issue was confidential or proprietary, that information had economic value in biopharmaceutical industry, that steps were taken by pharmaceutical companies to preserve or keep confidential this

information, and that used synonyms for the words “trade” and “secret” was not impermissible legal testimony, as would support admission of testimony in prosecution for conspiracy to steal trade secrets and receiving stolen trade secrets; testimony did not instruct that the measures taken were reasonable under the statute, and did not intrude upon court's authority to explain law to jury. 18 U.S.C.A. §§ 1832(a)(3), 1832(a)(5); Fed. R. Evid. 702, 704.

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OPINION

Slomsky, District Judge

I. INTRODUCTION

*1 The charges in this case arise from an alleged conspiracy to steal trade secrets from GlaxoSmithKline, LLC (“GSK”), a global healthcare and pharmaceutical research company, to use for a newly-established corporation in China and for other purposes. On March 28, 2018, a grand jury in the Eastern District of Pennsylvania returned a twelve-count Indictment against Defendant Gongda Xue alone. (Doc. No. 1.) The Indictment includes the following charges: one count of conspiracy to commit wire fraud, in violation of 18 U.S.C. § 1349; one count of conspiracy to steal trade secrets, in violation of 18 U.S.C. § 1832(a)(5); five counts of wire fraud, in violation of 18 U.S.C. § 1343; and five counts of receiving stolen trade secrets, in violation of 18 U.S.C. § 1832(a)(3). (Doc. No. 1 at 1.)

Before the Court is Gongda Xue's Motion in Limine to exclude at trial the testimony of three proposed expert witnesses for the Government: (1) Dr. John Baldoni; (2) Dr. Joseph Villafranca; and (3) Dr. Chester Myers. (Doc. No. 101.) In the Motion, Defendant seeks to preclude their testimony under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and Federal Rule of Evidence 702. (See id. at 1.) For reasons that follow, Dr. Baldoni, Dr. Villafranca, and Dr. Myers will be permitted to testify as experts in this case. However, they will not be permitted to use the term “trade secret” in their testimony. Accordingly, Defendant's Motion in Limine (Doc. No. 101) will be granted in part and denied in part.

II. BACKGROUND

A. Factual Background

This criminal case involves Defendant Gongda Xue and four other co-conspirators, charged elsewhere, and their alleged participation in a conspiracy to steal biopharmaceutical trade secrets from GlaxoSmithKline LLC (“GSK”). When the actions alleged in the Indictment (Doc. No. 1) occurred, Defendant Gongda Xue was a research scientist at the Friedrich Miescher Institute for Biomedical Research (“FMI”) in Basel, Switzerland. (Doc. No. 1 at 5.) Gongda Xue is the brother of co-conspirator Yu Xue. (Id.) Yu Xue worked as a senior-level manager at GSK in Upper Merion, Pennsylvania. (Id. at 6.) Because of her position at GSK, Yu Xue had “access to a wide array of GSK trade secret and confidential information.” (Id.) One particular trade secret that Yu Xue had access to was information about monoclonal antibodies, which are used to fight cancer and other diseases.¹ (Id. at 2.) This proprietary information was the result of considerable time, money, research, and development by GSK. (Id. at 2.) According to the Government, “GSK typically spent in excess of \$1 billion to research and develop each

biopharmaceutical product,” and any “research into possible pharmaceutical products, GSK's research data, GSK's research and development processes, and GSK's manufacturing processes are all trade secrets” belonged to GSK. (*Id.*)

*2 As alleged in the Indictment, Yu Xue emailed biopharmaceutical trade secrets and confidential information, which belonged to GSK, to Defendant Gongda Xue in Switzerland. (*Id.* at 8.) In turn, Gongda Xue provided Yu Xue with confidential information from his research institute, FMI. (*Id.*) Defendant then, *inter alia*, performed tests with the GSK trade secrets and confidential information, as well as with antibody samples sent to him from China by other co-conspirators. (*Id.*) Subsequently, Defendant sent the results of his research to the co-conspirators in China to benefit a new corporation founded by Yu Xue, Renopharma, Inc. (*Id.* at 9–10.)

B. The Motion in Limine

On September 27, 2021, Defendant filed a Motion in Limine to Exclude Expert Testimony. (Doc. No. 101.) In the Motion, Defendant seeks to preclude or otherwise limit testimony at trial from three of the Government's proposed expert witnesses: (1) Dr. Joseph Villafranca; (2) Dr. Chester Meyers; and (3) Dr. John Baldoni. (*Id.* at 1.) Defendant asserts that the testimony “purport[s] to convey opinions on an ultimate issue in this case, including whether documents do or do not contain trade secrets.” (*Id.*) Further, under *Daubert*, Defendant does not dispute that the proposed expert witnesses are qualified, but disputes “reliability” and “fit.” (Doc. No. 101 at 5.)

On October 1, 2021, the Government filed a Response. (Doc. No. 103.) And on October 4, 2021, the Court held a hearing on pretrial motions, including the instant Motion in Limine. At the hearing, the Court requested supplemental briefing on Defendant's Motion in Limine concerning admissibility under *Daubert*. On October 12, 2021, Defendant submitted a Supplemental Memorandum in Support of the Motion in Limine. (Doc. No. 106.) The Government filed a Response to the Supplemental Memorandum on October 18, 2021. (Doc. No. 107.)

The Motion is now fully briefed and ripe for disposition. Because the proposed expert testimony of Dr. Baldoni, Dr. Villafranca, and Dr. Myers are crucial to the outcome of this case, the Court will summarize the anticipated testimony of each in turn.

C. Proposed Testimony of Dr. John Baldoni

At the time of the actions alleged in the Indictment, Dr. John Baldoni was the Senior Vice President for Platform Design and Science at GSK. He has a Ph.D. in chemistry from Penn State University and has worked in the biopharmaceutical industry for more than 38 years. (Doc. No. 103 at 3.) According to the Government, “[h]e is one of the most knowledgeable people in the world on how to develop monoclonal antibodies.” (*Id.*) Dr. Baldoni previously testified before the federal grand jury that indicted Defendant Gongda Xue. (*Id.*) Further, he was among a team of scientists at GSK that reviewed the information that allegedly had been stolen by Gongda Xue and the other co-conspirators after the criminal actions of the co-conspirators alleged in the Indictment was uncovered. (*Id.* at 2–3.)

Although the Government plans to call Dr. Baldoni “primarily as a fact witness, [] there may be instances where he may testify in the form of an opinion.” (Doc. No. 103 at 3.) The Government anticipates that Dr. Baldoni will testify as follows:

The government anticipates that Dr. Baldoni will testify, as he testified previously, that the stolen documents, including the documents received by Gongda Xue, contained confidential and trade secret information belonging to GSK. He will describe that GSK invested a considerable amount of time, effort, and money to develop the intellectual property found in these documents. Dr. Baldoni will testify that Yu Xue did not have permission to steal the GSK documents. Dr. Baldoni will note that Yu Xue signed an agreement with GSK not to disclose GSK information without permission, which is standard practice in the industry. Dr. Baldoni will testify that Yu Xue received extensive training on her confidentiality obligations. Dr. Baldoni will testify that GSK would never give permission to share documents of this

nature to a person working for a competing organization or entity, such as Gongda Xue's employer, Friedrich Miescher Institute for Biomedical Research ("FMI"), or Gongda Xue's prospective employer, Novartis. Dr. Baldoni will testify to the steps GSK took to protect its intellectual property. Regarding the specific documents which Yu Xue sent to Gongda Xue, Dr. Baldoni will testify that these documents were often used at GSK to train new scientists and provided a general overview of how GSK develops and manufactures monoclonal antibodies. He will testify that these documents contained both trade secret and confidential information. Furthermore, he will testify that GSK is injured anytime it loses control over its intellectual property, including the manner in which it occurred in this case.

*3 (Id. at 4.)

D. Proposed Testimony of Dr. Joseph Villafranca

The second witness discussed in Defendant's Motion in Limine is Dr. Joseph Villafranca. Dr. Villafranca is a former Vice President of another large pharmaceutical company, Bristol Myers Squibb. (Doc. No. 103 at 4.) Dr. Villafranca has a Ph.D. in biochemistry from Purdue University. Also, he served as the Executive Vice President at Neose Technologies, a smaller biopharmaceutical company in Horsham, Pennsylvania. (Id.) Dr. Villafranca has spent over 45 years in the biopharmaceutical industry and taught biochemistry and molecular biology at Princeton University and Penn State University. (Id.)

Given his experience, the Government argues that "Dr. Villafranca is well[-]positioned to educate the jury on the biopharmaceutical industry and how the information which was stolen in this case would benefit Gongda Xue and injure GSK." (Id. at 4.) The Government anticipates that Dr. Villafranca will testify as follows:

The government anticipates that Dr. Villafranca will testify consistently with his testimony at the prior valuation hearing for Gongda Xue's co-conspirators. Dr. Villafranca will explain what monoclonal antibodies are and how they are developed. He will explain the differences between how large biopharmaceutical companies research and develop monoclonal antibodies as opposed to how small biopharmaceutical companies operate. He will explain how the documents which Yu Xue sent to Gongda Xue would benefit Gongda Xue in (a) applying for a job at Novartis and (b) creating his own biopharmaceutical company. Furthermore, he will explain how a company like GSK is injured when it loses control of its intellectual property, including the manner in which it occurred in this case.

(Id. at 4.)

E. Proposed Testimony of Dr. Chester Myers

The third proposed witness discussed in the instant Motion is Dr. Chester Myers. Dr. Myers worked as a protein scientist for over 35 years at companies such as Bristol-Myers Squibb, Neose Technologies, and SmithKline & French, which is "the predecessor company to GSK[]." (Doc. No. 103 at 5.) Additionally, he has worked as a consultant for biopharmaceutical companies of differing sizes. (Id.) He holds a Ph.D. in Biomedical Sciences from the City University of New York. (Id.) The Government anticipates that Dr. Myers will testify in the following manner:

While Dr. Villafranca will testify to the big picture, the government's fourth witness, Dr. Chester Meyers, will testify to the small details—in particular the specific trade secrets found in the documents sent from Yu Xue to Gongda Xue. Dr. Villafranca will testify that these documents contained trade secrets generally,

in contrast, Dr. Meyers will testify to the details. Dr. Meyers authored several reports, which have been provided to defense counsel, which describe the trade secrets contained in the stolen documents in great detail and his reasons for characterizing them as such. Dr. Meyers will summarize these reports for the jury at trial.

*4 (Id.)

III. STANDARD OF REVIEW

A. The Daubert Standard on the Admissibility of Expert Witness Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony. See FED. R. EVID. 702. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Id.

In Daubert v. Merrell Dow Pharmaceuticals, Inc., the United States Supreme Court provided the analytical framework to determine the admissibility of expert testimony under Federal Rule of Evidence 702. 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Daubert held that Rule 702 imposes a “gatekeeping” obligation on the trial court to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” Id. at 598, 113 S.Ct. 2786. Also under Rule 702, the United States Court of Appeals for the Third Circuit has held that it “has three major requirements: (1) the proffered witness must be an expert, *i.e.*, must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.” Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). These requirements are also referred to as “qualification, reliability and fit.” Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003).

1. Qualification

[1] [2] First, the Third Circuit has “interpreted Rule 702’s qualification requirement liberally.” Pineda, 520 F.3d at 244 (citing Schneider, 320 F.3d at 404; In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994)). Accordingly, a “broad range of knowledge, skills, and training qualify an expert.” Paoli, 35 F.3d at 741. Because both the “substantive” and “formal” qualifications of an expert are viewed liberally, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” Id. Thus, “it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate.” Pineda, 520 F.3d at 244 (quoting Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996)).

2. Reliability

[3] [4] [5] Turning to the “reliability” requirement, the Third Circuit has interpreted reliability “to mean that an expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” [Pineda](#), 520 F.3d at 244 (internal quotations omitted) (quoting [Paoli](#), 35 F.3d at 742). Notably, “[t]he evidentiary requirement of reliability is lower than the merits standard of correctness.” [Id.](#) at 744. Admissibility turns “on the expert’s methods and reasoning; credibility decisions arise after admissibility has been determined.” [Kannankeril v. Terminix Intern., Inc.](#), 128 F.3d 802, 806 (3d Cir. 1997). When examining expert testimony that is based on practical experience, rather than academic theories, “the [Daubert](#) factors (peer review, publication, potential error rate, etc.) simply are not applicable” because the reliability of testimony from a practical experience expert “depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” [States v. Fernwood Hotel and Resort](#), No. 12-906, 2014 WL 198568, at *3 (M.D. Pa. Jan. 15, 2014) (quoting [United States v. Hankey](#), 203 F.3d 1160, 1169 (9th Cir. 2000)).

3. Fit

*5 [6] [7] To satisfy the “fit” requirement, “the expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact.” [Schneider](#), 320 F.3d at 404. For expert testimony to meet the [Daubert](#) “fit” requirement, it must “assist the trier of fact to understand the evidence or to determine a fact in issue.” [FED. R. EVID. 702](#). “This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” [Daubert](#), 509 U.S. at 591, 113 S.Ct. 2786 (internal quotations omitted) (citing [United States v. Downing](#), 753 F.2d 1224, 1242 (3d Cir. 1985)).

B. Admissibility of Ultimate Issue Testimony

[8] [9] [Federal Rule of Evidence 704\(a\)](#) allows the expert to testify to the “ultimate issue” in the case. [Rule 704\(a\)](#) provides:

(a) In General—Not Automatically Objectionable. An opinion is not objectionable just because it embraces an ultimate issue.

[FED. R. EVID. 704\(a\)](#). “Although [Federal Rule of Evidence 704](#) permits an expert witness to give expert testimony that ‘embraces an ultimate issue to be decided by the trier of fact,’ an expert witness is prohibited from rendering a legal opinion.” [Berkeley Inv. Grp., Ltd. v. Colkitt](#), 455 F.3d 195, 217 (3d Cir. 2006). The reason for this prohibition is because it is the role of the trial judge to explain the law to the jury. [First Nat. State Bank of New Jersey v. Reliance Elec. Co.](#), 668 F.2d 725, 731 (3d Cir. 1981) (affirming trial court decision allowing expert witness to testify as to banking customs “to assist the trier of fact with bank and industry practices” but prohibiting expert from giving opinion “as to the legal duties arising therefrom”).

IV. ANALYSIS

In the instant Motion and Supplemental Brief in Support, Defendant contends that the expert testimony of Dr. Baldoni, Dr. Villafranca, and Dr. Myers should be barred because the second and third prongs of the Third Circuit’s test pursuant to [Rule 702](#) and [Daubert](#) are not met. In addition, Defendant asserts that experts should not be permitted to render an opinion that certain information is a “trade secret” because it would amount to impermissible testimony regarding the applicable law in this case. (See Doc. No. 10.) Further, Defendant requests a [Daubert](#) hearing. The Court will address each issue seriatim.

A. Drs. Baldoni, Villafranca, and Myers are qualified to testify as expert witnesses.

[10] First, the three proposed witnesses relevant to Defendant's Motion are qualified experts under the Third Circuit's standard, satisfying the first prong: "qualification." See [Pineda](#), 520 F.3d at 244. It should be noted that, here, Defendant does not dispute that the qualification prong is satisfied. In Defendant's Motion in Limine, he clarifies that he "does not challenge the experts' qualifications, but does object to the reliability and admissibility of their opinions." (Doc. No. 101 at 5.) Nevertheless, the Court will assess whether they are qualified to testify under the [Rule 702](#) standard set forth above.

The Third Circuit has consistently emphasized a liberal policy of admissibility under [Rule 702](#), which extends to the formal qualification of experts. See [Paoli II](#), 35 F.3d at 741; see also [Pineda](#), 520 F.3d at 243. In addition, the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." [Paoli II](#), 35 F.3d at 741. In [Hammond v. International Harvester Co.](#), 691 F.2d 646 (3d Cir. 1982), the Third Circuit found that an automobile and agricultural equipment salesperson was qualified to testify as an expert in a case involving a tractor because "[p]ractical experience as well as academic training and credentials may be the basis of qualification (as an expert witness)." [Id.](#) at 653 (quoting [Moran v. Ford Motor Co.](#), 476 F.2d 289, 291 (8th Cir. 1973) (internal quotation omitted)); see also [Lauria v. Nat'l R.R. Passenger Corp.](#), 145 F.3d 593, 599 (3d Cir. 1998) (foreman's years of experience with railroad track equipment, maintenance, and safety qualified him to testify as an expert on Amtrak's duty to maintain railroad track).

*6 Here, all three proposed witnesses are qualified as experts in the biopharmaceutical industry, as they each have served as executives at biopharmaceutical companies, had over 30 years of experience in the industry, are educated on the subject matter in this case, hold Ph.D. degrees in chemistry, biochemistry, and biomedical sciences, respectively, and learned confidentiality practices at pharmaceutical companies due to their experiences at similar companies such as GSK, Bristol-Myers Squibb, and Neose Technologies. (Doc. No. 103 at 3–5; see also Doc. No. 103-1, 103-2.) Their experience and qualifications in the biopharmaceutical industry make Drs. Baldoni, Villafranca, and Myers qualified to give expert opinions in this case, including whether certain information shared between Defendant and the other co-conspirators was confidential information or was information belonging to GSK that was to be kept secret.

B. The proposed testimony is reliable, as it is based on practical experience in the biopharmaceutical industry.

Second, the Court must assess whether the proposed expert testimony is reliable. As noted *supra*, the Third Circuit has interpreted reliability "to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." [Pineda](#), 520 F.3d at 244 (internal quotations omitted) (quoting [Paoli](#), 35 F.3d at 742). Notably, "[t]he evidentiary requirement of reliability is lower than the merits standard of correctness." [Id.](#) at 744. Admissibility turns "on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined." [Kannankeril](#), 128 F.3d at 806.

[11] Here, Defendant Gongda Xue asserts that the proposed experts are not reliable because their opinions on customs and procedures dealing with confidentiality at biopharmaceutical companies are not based on "methods and procedures of science," and are instead based on "subjective belief or unsupported speculation" without "good grounds" for their opinions. (Doc. No. 101 at 6 (citing [Paoli](#), 35 F.3d 717, 741 (3d Cir. 1994)).) Thus, Defendant asserts that the proposed testimony is not reliable because it does not satisfy the "good grounds" factors set forth in [Daubert](#) and [Paoli](#) regarding a testable hypothesis, peer review, publication, potential error rate. (Doc. No. 101 at 6.) Defendant then compares those factors to the proposed testimonies of Drs. Baldoni, Villafranca, and Myers, and argues that the Government has not shown that their anticipated opinions are based upon a reliable methodology. ([Id.](#) at 7.)

[12] As this Court has noted in a recent opinion regarding the "good grounds" factors and their relation to the reliability determination under [Daubert](#), the factors described by the defense and sourced from [Daubert](#) and [Paoli](#) are not applicable in every case:

It is well established, however, that these factors "are neither exhaustive nor applicable in every case." [Kannankeril](#), 128 F.3d at 806-07. The [Daubert](#) Court "made clear that its list of factors was meant to be helpful, not definitive." [Kumho Tire Co., Ltd. v. Carmichael](#), 526 U.S. 137, 151 [119 S.Ct. 1167, 143 L.Ed.2d 238] (1999). And when examining expert testimony

that is based on practical experience, rather than academic theories, “the Daubert factors (peer review, publication, potential error rate, etc.) simply are not applicable” because the reliability of testimony from a practical experience expert “depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” Fernwood Hotel and Resort, 2014 WL 198568, at *3 (quoting Hankey, 203 F.3d at 1169).

Christoforetti v. Bally's Park Place, Inc., No. CV 12-4687, 2021 WL 3879074, at *6 (D.N.J. Aug. 31, 2021). The same reasons compel the Court to reject Defendant's arguments on reliability here.

In this case, Drs. Baldoni, Villafranca, and Myers are expected to render opinions about proprietary information in the biopharmaceutical industry, as well as customs and practices for protecting information characterized as confidential. All three of the Government's witnesses have been executives at biopharmaceutical companies such as GSK and have several decades of experience in the industry. (Doc. No. 103 at 11.) From this practical experience, all three “understand the importance of intellectual property” in the industry, as well as “what types of information companies use to derive independent economic value,” and protect their information. (Id. at 11.)

*7 Furthermore, it is clear from the proposed testimony, as well as the former testimony of Drs. Villafranca and Myers at a valuation hearing on “loss” under the Federal Sentencing Guidelines regarding Defendant's co-conspirators, that the experts are familiar with the facts of the case and will be able to testify reliably whether the documents at issue contain information that is commonly known in the scientific community, or whether such information is proprietary and belonging to GSK. See United States v. Yu Xue, No. 16-22, 2020 WL 5645765, at *4 (E.D. Pa. Sept. 22, 2020). Although Dr. Baldoni has not testified before the Court previously, because he is a former executive at GSK, his testimony will be reliable as to the types of information that are regarded as proprietary in the industry and at the company. As noted by the Government, “part of Dr. Baldoni's duties at GSK was to understand what was considered by GSK to be a trade secret, and what could and could not be revealed in a public document, such as a patent application.”² (Doc. No. 107 at 6.) Thus, much of his testimony will be as a fact witness, as it is based upon his personal knowledge. (See id.)

In Defendant's Motion in Limine and Supplemental Memorandum in Support (Doc. Nos. 101, 106), tremendous attention is placed on the fact that this case is of a scientific nature. (See Doc. No. 101 at 6–9.) Along this vein, Defendant suggests that the proposed testimony of Drs. Baldoni, Villafranca, and Myers is unreliable because the experts have failed to base their opinions, characterized by Plaintiff as “scientific conclusions,” upon a certain methodology. (Doc. No. 106 at 10.) This attention on scientific methodology as a prerequisite to reliability, however, is misplaced in this case.

Instead, here, the experts will be testifying based upon their practical experiences in the industry. (See Doc. No. 103 at 3–5.) The experts will assist the jury in understanding what types of information is kept confidential, how this information is stored, what measures are taken to protect this information, the value of such information, and why the information is valuable. (See id.) This testimony is based on practical experience in the industry, rather than based on a particular scientific test, such as a DNA test. As noted by the Government, the experts would be “merely assisting the jury to understand how a particular piece of information fits th[e] definition” of proprietary information within the pharmaceutical industry, rather than giving an opinion based on the performance of a scientific test. (Id. at 11.) This practical experience, paired with the experts' careful review of the evidence in this case, meets the reliability prong under Rule 702. Further, the qualification of Drs. Baldoni, Villafranca, and Myers as experts in the biopharmaceutical industry, which Defendant notably does not dispute, supports the reliability of their opinions as experts in this field and in this case. (Doc. No. 101 at 5 (“Defendant does not challenge the experts' qualifications ...”).)

Therefore, the fact that the proposed expert testimony is not based on a testable theory or methodology subject to peer review does not preclude it from satisfying the second prong of the Third Circuit's test: “reliability.” This notwithstanding, as the Court will explain infra, the expert witnesses will not be permitted to use the term “trade secret” when testifying. Because the proposed testimony of the Government's experts is reliable, the Court will proceed to the third prong: “fit.”

C. The proposed testimony is “fit” to assist the trier of fact.

[13] Defendant further argues that the proffered expert testimony does not “fit” the facts of this case. (Doc. No. 101 at 9.) The Government counters this argument by noting that the proposed testimony of Drs. Baldoni, Villafranca, and Meyers will be helpful to the jury and assist their understanding of whether certain information is confidential and proprietary in the industry, or alternatively, is information that is widely available to the scientific community. (See Doc. No. 107 at 6.)

*8 To satisfy the “fit” requirement, “the expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact.” [Schneider](#), 320 F.3d at 404. As the Court has noted above, all three proposed witnesses are qualified as experts in the biopharmaceutical industry. Further, their practical experience working as executives for GSK or similar companies provides a reliable basis for them to testify whether the information shared between Gongda Xue and the co-conspirators was confidential in the industry. Biopharmaceutical secrets are precisely what the case against Defendant is about. Thus, the proposed testimony is fit to assist the trier of fact in this case.

Most importantly, when viewing the evidence and documents at issue in this case, the average juror before trial will not know, for example, “whether [information] is something out of a textbook which any doctoral student would know (and subsequently not a trade secret) or whether that procedure is a proprietary GSK trade secret (and not known to the scientific community).” (Doc. No. 107 at 6.) The Court agrees with the Government: “The jury cannot possibly be expected to know such a fact.” (*Id.*) Because this inquiry is central to the charges brought against Defendant Gongda Xue, the testimony of the three proposed experts will greatly assist the finder of fact and “fit,” satisfying the final prong of the Third Circuit’s test.

Thus, based upon the foregoing, the Court will admit the proposed testimony of Dr. Baldoni, Dr. Villafranca, and Dr. Myers as expert witnesses in this case because it is admissible under [Daubert](#) and [Rule 702](#). All three experts will be subject to cross-examination by Defendant. In addition, the arguments in Defendant’s Motion and Supplemental Memorandum regarding “reliability” and “fit” go to the weight of the experts’ testimony, rather than to its admissibility.

D. A [Daubert](#) hearing is not necessary on Defendant’s Motion.

[14] [15] [16] [17] A court is not required to hold a [Daubert](#) hearing, even if it is requested, if the record allows the court to rule on admissibility. “Courts have discretion to grant or deny such requests [for a [Daubert](#) hearing].” [Marcum v. Columbia Gas Transmission, LLC](#), 549 F. Supp. 3d 408, 418 n.3 (E.D. Pa. 2021) (citation omitted). As the Third Circuit has noted, “[a]n in limine hearing will obviously not be required whenever a [Daubert](#) objection is raised to a proffer of expert evidence. Whether to hold one rests in the sound discretion of the district court.” [Padillas v. Stork-Gamco, Inc.](#), 186 F.3d 412, 418 (3d Cir. 1999). A hearing is especially not necessary where a court “already ha[s] before it the depositions and affidavits of the [proposed] experts.” [Oddi v. Ford Motor Co.](#), 234 F.3d 136, 154 (3d Cir. 2000).

[18] At the evidentiary hearing on loss valuation held on April 30, 2019 and May, 1, 2019, Drs. Villafranca and Myers testified before this Court as Government witnesses against Defendant’s co-conspirators. See [United States v. Yu Xue](#), No. 16-22, 2020 WL 5645765, at *4 (E.D. Pa. Sept. 22, 2020) (summarizing testimonies of each Government witness). Their experience, qualifications, and expected testimony are known to the Court both through their previous testimony, as well as the extensive briefing regarding their proposed testimony by Defendant and the Government in this case. Both witnesses are familiar with the pertinent facts. Further, even though Dr. Baldoni has not previously testified in this case, he testified before the grand jury regarding Defendant Gongda Xue, and his expected testimony has been thoroughly briefed by both Defendant and the Government. Additionally, the Government has provided Defendant in discovery four reports authored by Dr. Myers, as well as FBI interview reports with Dr. Baldoni and other scientists at GSK about the documents at issue in this case. (Doc. No. 107 at 2.)

*9 As demonstrated above, the record in this case is sufficient regarding the proposed testimony of Dr. Baldoni, Dr. Villafranca, and Dr. Myers to allow the Court to rule on the Motion in Limine (Doc. No. 101). Therefore, Defendant’s request for a [Daubert](#) hearing will be denied.

E. Expert witnesses may not use the term “trade secret” when testifying at trial.

[19] In his Motion, Defendant also objects to the proposed testimony of Drs. Baldoni, Villafranca, and Myers that certain GSK information in this case is a “trade secret.” He submits that such testimony is impermissible as “ultimate issue” testimony and amounts to an instruction on the law. (Doc. Nos. 101 at 2–5, 106 at 2–4.) In response, the Government argues that the testimony regarding “trade secrets” is permissible for two reasons: first, experts may provide testimony that embraces the “ultimate issue” under [Federal Rule of Evidence 704](#); and second, the experts would not touch upon the legal definition of a “trade secret” and would solely use the term “trade secret” as it is understood in the biopharmaceutical industry. (Doc. Nos. 103 at 7–11, 107 at 3–7.)

May these expert witnesses use the term “trade secret” when testifying at trial to refer to the proprietary GSK information in this case? As set forth below, the Court concludes that they may not. The offenses relevant to this issue are in Count Two, which charges Defendant with conspiracy to steal trade secrets in violation of [18 U.S.C. § 1832\(a\)\(5\)](#), and in Counts Eight to Twelve, which charge Defendant with receiving stolen trade secrets, in violation of [18 U.S.C. § 1832\(a\)\(3\)](#).³

One of the “ultimate issues” in this case is whether the alleged misappropriated information falls within the statutory definition of “trade secret.” Under federal law, the theft of trade secrets is prohibited under [18 U.S.C. § 1832\(a\)](#). However, the statutory definition of “trade secret” as it is used in [§ 1832\(a\)](#) is set forth in a different statute: [18 U.S.C. § 1839](#). To find that information constitutes a “trade secret” under [§ 1839](#), the jury must find that:

- (A) the owner thereof has taken reasonable measures to keep such information secret; and
- (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information[.]

***10** [18 U.S.C. § 1839 \(3\)\(A\)–\(B\)](#).

As noted *supra*, expert witnesses may provide testimony that embraces an ultimate issue pursuant to [Federal Rule of Evidence 704\(a\)](#). Nevertheless, when providing such testimony, “an expert witness is prohibited from rendering a legal opinion.” [Berkeley Inv. Grp., Ltd. v. Colkitt](#), 455 F.3d 195, 217 (3d Cir. 2006). When a case involves customs or practices of a particular industry, “the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party’s compliance with customs and practices that implicate legal duties.” [Id.](#) at 218.

In his Motion, Defendant opposes the use of the term “trade secret” by the witnesses to refer to confidential information, arguing that this is a legal conclusion.⁴ (Doc. No. 101 at 3–5.) The United States Court of Appeals for the Third Circuit has not ruled on the issue of whether an expert witness may testify using the term “trade secret,” in either a civil or criminal case. Nevertheless, the Third Circuit has held that courts commonly exclude “legal terms of art” from expert testimony. [Flickinger v. Toys R Us–Delaware, Inc.](#), 492 F. App’x 217, 224 (3d Cir. 2012). In [Flickinger](#), the Third Circuit held that the district court correctly excluded the term “exclusive control” from expert testimony in a negligence case, as it is a phrase with a legal definition that the jury would ultimately have to decide upon. The Third Circuit noted:

Here, the District Court allowed testimony to demonstrate that Toys “R” Us was the only entity that filled the bin or maintained it. It also allowed testimony showing that many other people had access to it. This gave the jury the information needed to determine whether Toys “R” Us had “exclusive control.” But the Court did not allow experts to provide testimony using the legal phrase, “exclusive control.” Similarly, the paragraphs excluded by the Court in the experts’ reports offered legal opinions as to “exclusive control,” “dangerous condition,” “substantial cause,” and “negligence.” These phrases are legal terms of art that courts commonly hold cannot be the subject of expert testimony. *See* 4 Jack B. Weinstein & Margaret

A. Berger, Weinstein's Federal Evidence, § 704.04[1] (Joseph M. McLaughlin, ed., Matthew Bender 2d ed. 2011). The District Court therefore did not exceed its discretion in prohibiting this testimony and evidence from reaching the jury.

Flickinger v. Toys R Us-Delaware, Inc., 492 F. App'x 217, 224 (3d Cir. 2012).

*11 District courts in the Third Circuit have followed suit, precluding experts from using legal terms of art that are at issue in the case. See, e.g., Dalgic v. Misericordia Univ., No. 3:16-CV-0443, 2019 WL 2867236, at *13 (M.D. Pa. July 3, 2019) (holding improper for expert to testify using the term “proximate cause”); Perez v. Townsend Eng'g Co., 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding expert witness from using legal terms of art, such as in a products liability case that the machine at issue was “defective,” “unreasonably dangerous,” or was the “proximate cause” of [the plaintiff's] injury, as this could lead the jury to be prejudiced against the defendant). For example, one legal term that district courts commonly exclude from expert testimony is “bad faith.” See, e.g., Gallatin Fuels, Inc. v. Westchester Fire Ins. Co., 410 F. Supp. 2d 417, 422 (W.D. Pa. 2006) (“Although expert testimony may be helpful to the fact-finder in a bad faith case, an expert may not give an opinion as to the ultimate legal conclusion that an insurer acted in ‘bad faith’ in violation of applicable law.”); McCrink v. Peoples Benefit Life Ins. Co., No. 04-01068, 2005 WL 730688, at *4 (E.D. Pa. Mar. 29, 2005) (“Of course, the [expert] report's ultimate conclusion that defendant acted in bad faith is inadmissible for embracing a legal conclusion.”).

A review of decisions from other Circuit Courts of Appeal demonstrates that courts outside the Third Circuit also have precluded witnesses from using terms with a specialized legal meaning that is more precise than the lay understanding of the term. For example, in Burkhart v. Washington Metropolitan Area Transit Authority, 112 F.3d 1207, 1212 (D.C. Cir. 1997), the District of Columbia Circuit held, in a case under the Americans with Disabilities Act (“ADA”), that an expert's use of the term “as effective,” a phrase “lifted directly from the text of the Attorney General's regulations implementing the ADA,” was an inadmissible legal conclusion. Id. at 1213. The D.C. Circuit determined that use of the term “as effective” by the expert witness was impermissible because it was a legal “term of art with a meaning ‘separate’ and ‘distinct’ from the vernacular.” Id. at 1213 (citing Torres v. County of Oakland, 758 F.2d 147, 151 (6th Cir. 1985)).

In its decision, the D.C. Circuit cited precedent from the Sixth Circuit Court of Appeals, which has the same approach to legal terms on ultimate issues:

The Sixth Circuit has concluded that “[t]he best resolution of this type of problem is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular. If they do, exclusion is appropriate.” Torres, 758 F.2d at 151. Applying this principle in a Title VII suit, the Torres court concluded that it was improper to permit an expert to testify as to whether the plaintiff “had been discriminated against because of her national origin.” Id. As the court explained, the expert's actual testimony constituted a legal conclusion for two reasons: it tracked the language of the applicable statute, and the term “discrimination” has a specialized legal meaning that is more precise than the lay understanding of the term. Id. However, the court noted in [dicta] that it would have been permissible for the expert to testify as to whether “national origin ‘motivated’ the hiring decision.” Id. Testimony phrased as such would “address the factual issue of ... intent without implicating any legal terminology.” Id.

Burkhart, 112 F.3d at 1212. Thus, the court emphasized that using the term “motivated” to describe the hiring decision, instead of “because of national origin,” was permissible because the latter was taken directly from the language of Title VII and therefore was an impermissible legal conclusion under Rule 704. See id.

The Fourth Circuit has taken a similar approach. In United States v. Barile, 286 F.3d 749, 759 (4th Cir. 2002), the issue was whether a district court correctly precluded an expert from using the term “materiality.” Id. at 760. On appeal, the Fourth Circuit held that the district court correctly excluded expert testimony regarding whether a defendant's submission to the Food and Drug Administration contained “materially misleading statements.” Id. at 761. The Fourth Circuit held that the phrase “ ‘materially

misleading statements' arguably constitutes a legal conclusion because materiality has a specialized legal meaning, and it is therefore within the district court's discretion to exclude such testimony." Id.

*12 Here, in response to Defendant's argument, the Government cites several cases from other Circuits, arguing that courts regularly allow expert witnesses to use the term "trade secret" in their testimony. See United States v. Shanshan Du, 570 F. App'x 490 (6th Cir. 2014) (affirming conviction for multiple counts relating to theft of trade secrets because the conviction was supported, *inter alia*, by testimony from multiple witnesses that the specific information in the documents was not in the public domain); Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881 (5th Cir. 2013) (holding district court properly allowed a software expert, who identified whether certain evidence was a trade secret, to testify because he was qualified as expert); United States v. Aleynikov, 785 F. Supp. 2d 46, 68 (S.D.N.Y. 2011) (noting Government's expert witness testified as to "the secretive nature of the business" in a case involving the trading industry, which supported conviction under statutory theft of trade secrets).

None of these decisions, however, dealt with a direct challenge to the admissibility of the term "trade secret." Only in Wellogix was the term "trade secret" used by the court when describing an expert witness's testimony. Wellogix, 716 F.3d at 881. In Shanshan Du, the court noted and apparently approved of "testimony from multiple witnesses that the specific information in the documents was not in the public domain." Shanshan Du, 570 F. App'x at 501. And in Aleynikov, the court noted that an expert testified "about the secretive nature of the business" and that "anything would be perceived to be giving away a secret." Aleynikov, 785 F. Supp. 2d at 70. But, the term "trade secret" was not used by the court in describing the expert testimony in the latter two cases. Moreover, nothing in the latter two cases supports the notion that the expert witnesses used the words "trade secrets" at trial. Taken together, the three cases relied upon by the Government are not persuasive on whether the phrase "trade secret" can be used at trial.

Thus, the Court concludes that the term "trade secret" is a term of art with specialized legal meaning, especially in this case. The term "trade secret," as it applies here, is a term defined statutorily under § 1839, set forth *supra*, and is an element of the offenses charged in Counts Two, Eight, Nine, Ten, Eleven, and Twelve. The Court will instruct the jury on the definition of "trade secret" under § 1839. Ultimately, the jury must decide whether the Government has proved beyond a reasonable doubt that the documents in issue contain "trade secrets," after carefully applying the facts they find to the law. Thus, the expert witnesses may not testify using the term "trade secret" because doing so "would usurp the District Court's pivotal role in explaining the law to the jury." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d at 217.

[20] The Government further posits that it is permissible for their witnesses to use the term "trade secret" by arguing that "the term 'trade secret' is understood and used in the biopharmaceutical industry." (Doc. No. 107 at 6.) While this may be true, the term "ha[s] a separate, distinct and specialized meaning in the law different from that present in the vernacular." Torres, 758 F.2d at 151. Accordingly, exclusion is warranted. And preventing the expert witnesses from using the term "trade secret" will ensure that Defendant Gongda Xue is not unduly prejudiced under Federal Rule of Evidence 403, as the probative value in using the phrase is outweighed by the danger of the jury repeatedly hearing "trade secret" in the Government's proffered expert testimony. FED. R. EVID. 403.

[21] So what can Government witnesses say at trial to prove that the documents in issue contain "trade secrets"? The Government's witnesses may testify, *inter alia*, that the information at issue was confidential or proprietary information, that the information has economic value in the industry, and that steps are taken by GSK and other companies to preserve or keep confidential this information. Though Defendant contends that testimony about security measures, or the "reasonable measures" taken "to keep such information secret," would contain legal conclusions under the § 1839 definition of "trade secret," this is unpersuasive. (See Doc. No. 106 at 3–4.) As explained by the Government concerning "reasonable measures:"

*13 Dr. Villafranca and Dr. Meyers will offer no opinions in this regard. Dr. Baldoni will testify as a fact witness to the measures which GSK took to keep their information secret. For example, he will

testify to the physical security of the Upper Merion facility, the computer security [methods] employed by GSK at the time the documents were stolen, and the extensive amount of training which GSK employees received about the need to keep GSK information confidential. Dr. Baldoni will not offer an opinion as to whether all of these measures were “reasonable.” The [G]overnment agrees with the [D]efendant that the conclusion whether these measures were “reasonable” is within the province of the jury.

(Doc. No. 107 at 8.) This testimony about security measures is permissible support for the Government's case. It does not instruct that the measures were “reasonable” under the statute, nor does it intrude upon the Court's authority to explain the law to the jury.

Therefore, while the Government's witnesses may testify regarding customs and practices in the biopharmaceutical industry, the term “trade secret” may not be used by them.⁵ Additionally, the witnesses may not use the term “secret.” As an alternative to “trade secret” or “secret,” the witnesses may testify that the information was “confidential” or “proprietary,” about any steps taken to protect the confidentiality of the information, and about industry customs and practices. The witnesses may also use synonyms for the words “trade” and “secret.” During trial, the Court will give a jury instruction that it is for the jury to decide whether or not the information at issue in the case is a “trade secret” under § 1839, as “trade secret” is a term with a specialized legal meaning. In this regard, if the parties wish to provide the Court with a proposed instruction, they may file the requested jury instruction of record for the Court's consideration.

V. CONCLUSION

For the foregoing reasons, Defendant's Motion in Limine to Exclude Expert Testimony (Doc. No. 101) will be granted in part and denied in part. An appropriate order follows.

All Citations

--- F.Supp.3d ----, 2022 WL 1027634

Footnotes

1 In the Indictment, the Government described monoclonal antibodies and their use further:

One product under development [at GSK] was a monoclonal antibody (“mAB”) designed to link to HER3 receptors on human body cells. In certain forms of [cancer](#), HER3 receptors are “overexpressed,” that is, human body cells contain too many of these receptors. This overexpression contributes to the development of [cancer](#). The proposed antibody would bind with or otherwise impact the overexpressed HER3 receptor cells to eliminate the [cancer](#), slow its development, or help to prevent the [cancer](#) from returning.

(Doc. No. 1 at 2.)

2 As noted above and discussed [infra](#), Dr. Baldoni will not be permitted to give his opinion that information in a GSK document is a “trade secret.”

3 [Section 1832\(a\)](#) states in relevant part:

(a) Whoever, with intent to convert a trade secret, that is related to a product or service used in or intended for use in interstate or foreign commerce, to the economic benefit of anyone other than the owner thereof, and intending or knowing that the offense will, injure any owner of that trade secret, knowingly—

(1) steals, or without authorization appropriates, takes, carries away, or conceals, or by fraud, artifice, or deception obtains such information;

....

(3) receives, buys, or possesses such information, knowing the same to have been stolen or appropriated, obtained, or converted without authorization; [or]

....

(5) conspires with one or more other persons to commit any offense described in paragraphs (1) through (3), and one or more of such persons do any act to effect the object of the conspiracy,

shall, except as provided in subsection (b), be fined under this title or imprisoned not more than 10 years, or both.

18 U.S.C. § 1832.

- 4 In the Motion, Defendant loosely comments that using the term “trade secret” would “constitute speculative opinion testimony about another individual's state of mind,” but does not otherwise directly assert that the expert witnesses will impermissibly testify regarding Defendant's mental state, which is barred under [Federal Rule of Evidence 704\(b\)](#). (Doc. No. 101 at 4.) But as confirmed in the Government's response, “[t]he [G]overnment's expert witnesses in this case will not testify about the defendant's mental state.” (Doc. No. 103 at 9.) Therefore, this is not an issue here.
- 5 It should be noted, however, that if a witness testifying on behalf of Defendant opens the door by using the term “trade secret,” the Government's witnesses will be permitted to testify using the term.

2022 WL 334169
United States District Court, D. New Jersey.
Lauren MASTRIPOLITO, Plaintiff,
v.
JEFFRESON HEALTH-NEW JERSEY, Defendant.
CIVIL ACTION NO. 19-21708
|
Filed 02/02/2022

Synopsis

Background: Employee brought action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer, alleging hostile work environment. Employer moved in limine to exclude evidence.

Holdings: The District Court, Edwardo C. Robreno, J., held that:

- [1] employment lawyer's expert report containing several pages detailing recitation of caselaw and relevant legal standard for vicarious liability was not admissible;
- [2] employment lawyer's expert opinion on relevant nonlegal industry standards for conducting proper and appropriate investigation was admissible;
- [3] evidence of prior written discipline that co-employee assailant received during his employment with employer and its predecessor was not admissible;
- [4] incident report and related corrective action notice was not admissible;
- [5] plaintiff could not offer e-mail for truth of matter asserted in e-mail, but it could be used as evidence that employer did not conduct proper investigation; and
- [6] probative value of e-mail was not substantially outweighed by danger of confusing issues.

Motion granted in part and denied in part.

Procedural Posture(s): Motion in Limine.

West Headnotes (17)

[1] **Federal Civil Procedure** 🔑 **Motions in Limine**

Motions in limine allow the trial court to rule in advance of trial on the admissibility and relevance of certain forecasted evidence.

[2] **Federal Civil Procedure** 🔑 Motions in Limine

Trial court should exclude evidence on a motion in limine only when the evidence is clearly inadmissible on all potential grounds.

[3] **Federal Civil Procedure** 🔑 Motions in Limine

Party seeking to exclude evidence on a motion in limine bears the burden of demonstrating that the challenged evidence is inadmissible on any relevant ground.

[4] **Evidence** 🔑 Matters Directly in Issue

Employment lawyer's expert report containing several pages detailing recitation of caselaw and relevant legal standard for vicarious liability, offered to help trier of fact to determine whether investigation was carried out in manner that impeded discovery of serious and significant harassment, was not admissible, in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5-1 et seq.; Fed. R. Evid. 702.

[5] **Civil Rights** 🔑 Knowledge or notice; preventive or remedial measures

Employer liability for co-worker harassment exists under Title VII only if employer failed to provide reasonable avenue for complaint or, alternatively, if employer knew or should have known of harassment and failed to take prompt and appropriate remedial action. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.

[6] **Civil Rights** 🔑 Knowledge or notice; preventive or remedial measures

Title VII does not require that investigations into sexual harassment complaints be perfect; rather, to determine whether remedial action was adequate, court must consider whether action was reasonably calculated to prevent further harassment. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.

[7] **Civil Rights** 🔑 Knowledge or notice; preventive or remedial measures

An investigation might be carried out in a way that prevents the discovery of serious and significant harassment by an employee such that the remedy chosen by the employer could not be held under Title VII to be reasonably calculated to prevent the harassment. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.

[8] **Evidence** 🔑 Ultimate issues in general

Though the district court has discretion to determine whether expert testimony will help the trier of fact, the district court must ensure that an expert does not testify as to the governing law of the case, as an expert witness is prohibited from rendering a legal opinion; the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties. Fed. R. Evid. 702.

[9] **Evidence** 🔑 Customs and usages; industry practice

Employment lawyer's expert opinion on relevant nonlegal industry standards for conducting proper and appropriate investigation, to help trier of fact to determine whether investigation was carried out in manner that impeded discovery of serious and significant harassment, was admissible, in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment, although he could not offer ultimate conclusion about whether employer's conduct violated relevant industry standards. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5–1 et seq.; Fed. R. Evid. 702.

[10] Evidence 🔑 Factors, Tests, and Standards in General

When considering whether expert may testify, trial judge must: confirm witness is qualified expert; check proposed testimony is reliable and relates to matters requiring scientific, technical, or specialized knowledge; and ensure expert's testimony is sufficiently tied to facts of case, so that it fits dispute and will assist trier of fact. Fed. R. Evid. 702.

[11] Evidence 🔑 Other Crimes, Wrongs, or Acts

Evidence of prior written discipline that co-employee assailant received during his employment with employer and its predecessor, such as attendance issues, performance write-ups, absences, and issues related to his not taking patient's vital signs correctly, did not have proper non-propensity purpose that was admissible, in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment, since employee sought to use that evidence to show that assailant likely would break rules with respect to employee because he had broken rules in past. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5–1 et seq.; Fed. R. Evid. 404(b).

[12] Evidence 🔑 Other Crimes, Wrongs, or Acts

To be admissible, prior bad acts evidence must have proper purpose, it must be relevant, its probative value must outweigh prejudicial effect, and district court must charge jury to consider evidence only for limited purpose for which it was admitted. Fed. R. Evid. 404(b).

[13] Evidence 🔑 Other Crimes, Wrongs, or Acts

Prior bad acts evidence must be relevant to a non-propensity purpose to be admissible. Fed. R. Evid. 404(b).

[14] Evidence 🔑 Other Crimes, Wrongs, or Acts

When a proponent contends that the evidence is both relevant and admissible for a proper purpose, the proponent must clearly articulate how that evidence fits into a chain of logical inferences, no link of which may be the inference that the defendant has the propensity to commit the crime charged. Fed. R. Evid. 404(b).

[15] Evidence 🔑 Tendency to mislead or confuse; prejudicial effect

Any probative value of co-employee's decade-old somewhat illegible incident report based on complaint of assault by patient that did not clearly describe of what co-employee had been accused was substantially outweighed by danger of unfair prejudice, and therefore incident report and related corrective action notice was not admissible, in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5–1 et seq.; Fed. R. Evid. 403.

[16] Evidence 🔑 Particular statements or assertions

Plaintiff employee could use e-mail to supervisor from staff member of human resources department, recapping her interview with co-worker who complained about previously being sexually harassed by same person who subsequently sexually assaulted plaintiff, for limited purpose of supporting argument that supervisor failed to consider material information provided by her staff members, and therefore did not conduct proper investigation because she did not follow-up on that e-mail or otherwise acknowledge it, but plaintiff could not offer e-mail for truth of matter asserted in e-mail, in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5-1 et seq.; Fed. R. Evid. 801.

[17] Evidence 🔑 Discrimination

Probative value of e-mail to supervisor from staff member of human resources department, recapping her interview with co-worker who complained about previously being sexually harassed by same person who sexually subsequently assaulted plaintiff, for limited purpose of supporting argument that supervisor failed to consider material information provided by her staff members, and therefore did not conduct proper investigation because she did not follow-up on that e-mail or otherwise acknowledge it, was not substantially outweighed by danger of confusing issues, and therefore it was admissible in employee's action under Title VII and New Jersey's Law Against Discrimination (NJLAD) against employer alleging hostile work environment, particularly since limiting instruction would cure any danger of confusion. Civil Rights Act of 1964, § 701 et seq., 42 U.S.C.A. § 2000e et seq.; N.J. Stat. Ann. § 10:5-1 et seq.; Fed. R. Evid. 403.

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AMENDED MEMORANDUM

EDUARDO C. ROBRENO, District Judge

I. INTRODUCTION

*1 Plaintiff Lauren Mastripolito brings this action against Defendant Jefferson Health - New Jersey alleging that Defendant created a hostile work environment. Plaintiff alleges that she was sexually assaulted by a coworker (Anthony Hailey) at Defendant's Washington Township Dialysis Center and, after reporting the alleged assault, Defendant failed to take appropriate remedial measures in violation of Title VII of the Civil Rights Act of 1964 and New Jersey's Law Against Discrimination ("NJLAD").

Before this Court is Defendant's motion in limine to (A) exclude the testimony and report of Plaintiff's expert Michael Torchia, (B) exclude evidence of the criminal history of Anthony Hailey, (C) exclude evidence of Anthony Hailey's discipline record,

(D) exclude evidence of a prior incident report involving Anthony Hailey, and (E) exclude evidence of statements Anthony Hailey made to another coworker, Mary Pentz, over a decade prior. The Court held a hearing on these issues on January 4, 2022.

For the following reasons, Defendant's motion will be granted in part and denied in part.

II. LEGAL STANDARD

[1] [2] [3] Motions in limine “allow the trial court to rule in advance of trial on the admissibility and relevance of certain forecasted evidence.” United States v. Tartaglione, 228 F. Supp. 3d 402, 406 (E.D. Pa. 2017) (citing Bradley v. Pittsburgh Bd. of Educ., 913 F.2d 1064, 1069 (3d Cir. 1990)). “The trial court should exclude evidence on a motion in limine only when the evidence is clearly inadmissible on all potential grounds.” Id. (citing Leonard v. Stemtech Health Sciences, Inc., 981 F. Supp. 2d 273, 276 (D. Del. 2013)). The party seeking to exclude evidence “bears the burden of demonstrating that the challenged evidence is inadmissible ‘on any relevant ground.’ ” Apotex, Inc. v. Cephalon, Inc., No. 2:06-CV-2768, 2017 WL 2362400, at *2 (E.D. Pa. May 31, 2017) (quoting Leonard, 981 F. Supp. 2d at 276).

III. DISCUSSION

A. Motion to Exclude the Expert Report of Michael Torchia

[4] Defendant moves to exclude the expert report of Michael Torchia. Michael Torchia is an employment lawyer based in Pennsylvania who has previously testified as an expert on workplace investigation in other cases. In this case, Mr. Torchia authored a report on whether Defendant properly conducted a workplace investigation relating to complaints made by Plaintiff.

[5] [6] [7] Plaintiff offers Mr. Torchia's report on an issue related to vicarious liability. “[E]mployer liability for co-worker harassment exists only if the employer failed to provide a reasonable avenue for complaint or, alternatively, if the employer knew or should have known of the harassment and failed to take prompt and appropriate remedial action.” Huston v. Procter & Gamble Paper Prod. Corp., 568 F.3d 100, 104 (3d Cir. 2009). “[T]he law does not require that investigations into sexual harassment complaints be perfect. Rather, to determine whether the remedial action was adequate, we must consider whether the action was reasonably calculated to prevent further harassment.” Knabe v. Bury Corp., 114 F.3d 407, 412 (3d Cir. 1997) (internal citations and quotation marks omitted). However, an “investigation might be carried out in a way that prevents the discovery of serious and significant harassment by an employee such that the remedy chosen by the employer could not be held to be reasonably calculated to prevent the harassment.” Id. at 414. The Third Circuit emphasized that “an employer can be held liable if a faulty investigation renders its subsequent remedial action inadequate, i.e., not reasonably calculated to prevent further harassment.” Id. Plaintiff seeks to offer Mr. Torchia's testimony to help the trier of fact to determine whether the investigation was carried out in manner that impeded “the discovery of serious and significant harassment.” Id.

*2 Defendant does not contest Mr. Torchia's credentials. Rather, Defendant argues that Mr. Torchia's report goes to the ultimate legal issue of whether Defendant's actions were “reasonably calculated to prevent further harassment,” and allowing Mr. Torchia to testify would not assist the trier of fact. Def. Mot. at 3, ECF No. 70-1 (emphasis omitted). These will be addressed in turn.

1. Whether Mr. Torchia's Report Contains Legal Conclusions

[8] Though “[t]he District Court has discretion to determine whether expert testimony will help the trier of fact ... the District Court must ensure that an expert does not testify as to the governing law of the case” as “an expert witness is prohibited from rendering a legal opinion.” Berkeley Inv. Grp. Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). “[T]he line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties.” Id. at 218.

The Third Circuit has permitted experts to “opine on established industry customs and standards, provided the testimony stops short of defining the legal duties arising from industry customs or opining on whether the defendant has complied with those duties.” Jordan v. Temple Health Sys., Inc., No. 16-5561, 2018 WL 3649019, at *2 (E.D. Pa. Aug. 1, 2018) (citing Berkeley, 455 F.3d at 218). In Berkeley, a case involving whether the defendant made material misrepresentations with respect to an offshore securities purchase agreement, the Third Circuit held that an expert in offshore securities transactions could testify about the “customs and business practices in the securities industry at the time the parties entered into the Agreement” as this could “provide[] an important context which will aid the jury in determining whether [appellee] had the requisite scienter at the time to evade the registration requirements.” 455 F.3d at 218. However, the expert would not be permitted to “testify as to whether [appellee] complied with legal duties that arose under federal securities laws.” Id.

Similarly, in First Nat. State Bank of New Jersey v. Reliance Elec. Co., the Third Circuit affirmed a district court's decision to permit an expert on the Uniform Commercial Code to testify as to the customs of the banking industry “to assist the trier of fact with bank and industry practices” and to “provide[] information on whether the [b]ank's conduct warranted status akin to that of a holder in due course in light of banking practices.” 668 F. 2d 725, 731 (3d Cir. 1981). However, the expert was not permitted to testify about the legal duties arising from banking customs, or to make an ultimate conclusion on whether the “[b]ank lacked good faith and/or had notice of claims, thereby denying it holder-in-due-course status.” Id.

Defendant argues that Mr. Torchia's report includes several pages that outline the relevant caselaw and legal standard that should be excluded. Defendant points to Jordan, where a court in the Eastern District of Pennsylvania excluded an expert report authored by Mr. Torchia that described the federal law and relevant regulations relating to the American with Disabilities Act (“ADA”) and EEOC in an ADA case. 2018 WL 3649019, at *1. In that case, the court excluded Mr. Torchia's opinion because “[t]he majority of the report consists of recitations of case law and federal regulations” and the only opinions “relate directly to the legal duties existing under the ADA, and unduly infringe on the judge's lawgiving and jury's fact-finding.” Id. at *2. Because Mr. Torchia's proffered testimony did not contain any opinions regarding industry standards, the court found that it would not “ ‘help the trier of fact to understand the evidence’ beyond what will already be provided by fact witnesses and this Court's legal instructions.” Id. at *3 (citing Fed. R. Evid. 702).

*3 Here, Mr. Torchia's report does contain several pages detailing recitation of caselaw and the relevant legal standard. This portion of Mr. Torchia's report is not admissible. However, Mr. Torchia's report also includes relevant information regarding the industry standard, the admissibility of which is discussed below.

2. Whether Mr. Torchia's Report Will Assist the Trier of Fact

[9] [10] Defendant argues that the remainder of Mr. Torchia's testimony regarding the relevant industry standard will not be helpful to the trier of fact. When considering whether an expert may testify the trial judge must:

- (1) confirm the witness is a qualified expert; (2) check the proposed testimony is reliable and relates to matters requiring scientific, technical, or specialized knowledge; and (3) ensure the expert's testimony is ‘sufficiently tied to the facts of the case,’ so that it ‘fits’ the dispute and will assist the trier of fact.

UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 832 (3d Cir. 2020) (quoting Daubert v. Merrell Dow Pharm., 509 U.S. 579, 591, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)). Defendant argues that Mr. Torchia is unable to satisfy the third requirement in that his testimony will not “fit” the dispute or “assist the trier of fact.” Id. This condition relates “primarily to relevance,” so the expert's testimony must be related to the issues at hand. Daubert, 509 U.S. at 591, 113 S.Ct. 2786.

Defendant first argues that the portion of Mr. Torchia's report that discusses the industry standard is not relevant to the issues at hand. Defendant avers that because “the law does not require that investigations into sexual harassment complaints be perfect,” an opinion on the adequacy of the investigation is unnecessary. Knabe, 114 F.3d at 412. As noted, “to determine whether the remedial action was adequate, we must consider whether the action was reasonably calculated to prevent further harassment.”

Id. (internal citations and quotation marks omitted). However, an “investigation might be carried out in a way that prevents the discovery of serious and significant harassment by an employee such that the remedy chosen by the employer could not be held to be reasonably calculated to prevent the harassment.” Id. at 414. Thus, Mr. Torchia's testimony on the relevant industry standards may help the trier of fact to determine whether the investigation was carried out in manner that impeded “the discovery of serious and significant harassment.” Id.

Defendant additionally relies upon several cases in which courts excluded expert testimony on the sufficiency of an employer's investigation, finding that such testimony would not assist the trier of fact. Defendant points to Knox v. PPG Industries, Inc., a case where the Western District of Pennsylvania excluded testimony from an expert in workplace investigations, finding that the jury was capable of understanding whether the defendant conducted a flawed investigation and that the expert's testimony “would suggest a higher standard [for investigations] than what the law requires.” No. 15-1434, 2018 U.S. Dist. Lexis 42508, at *3 (W.D. Pa. March 15, 2018). However, Knox is inapposite as there is no argument here that Mr. Torchia's report suggests a higher standard for investigations than what is legally required.

Defendant also relies on Crawford v. George Lynch, Inc., a case where the District of Delaware considered whether to exclude an expert report that discussed whether the defendant-employer deviated from standard employer practices. No. 10-949, 2013 WL 6504361, at *1 (D. Del. Dec. 9, 2013). Crawford specifically dealt with whether an employer exercised reasonable care to prevent and correct harassing behavior in the context of the Faragher-Elterth affirmative defense as applied to a supervisory harassment claim. Id. The Crawford court excluded portions of the expert's report that involved industry standards because the report “generally refer[red] to ‘standard practice’ or ‘standards in the industry’ that are ‘typically put in place by organizations’” without explaining the methodology that governs the sufficiency of the industry standards. Id. at *2. Here, Crawford is also inapposite because the Defendant has not disputed Mr. Torchia's methodology.

*4 In response, Plaintiff points to several cases where courts have found that expert testimony regarding an employer's response to complaints of harassment were admissible. See, e.g., Fantazzi v. Temple Univ. Hosp., Inc., No. 00-3175, 2003 U.S. Dist. Lexis 9731, at *5 (E.D. Pa. May 13, 2003) (allowing expert testimony “that [defendant] failed to take adequate steps to prevent retaliation against Plaintiff,” but excluding the expert's “proposed legal conclusion that [defendant] retaliated against Plaintiff”); Blakely v. Continental Airlines, No. 93-2194, 1997 WL 1524797 *4, 1997 U.S. Dist. LEXIS 22074, *9 (D.N.J. Sept. 9, 1997) (finding the expert's testimony “will be limited to the general policies and practices a company may undertake in an effort to be effective in preventing and addressing allegations of sexual harassment”).

Significantly, Plaintiff points to two recent cases where Mr. Torchia was permitted to offer his opinion on the relevant industry standards. In Vandergrift v. City of Philadelphia, the plaintiff brought a claim of hostile work environment and argued that the defendant ineffectively handled an investigation pertaining to plaintiff's claims of sexual harassment and discrimination. 228 F. Supp. 3d 464, 488 (E.D. Pa. 2017). The defendant had argued that it exercised reasonable care to prevent and correct any harassment and discrimination. In its decision resolving summary judgment, the Eastern District of Pennsylvania allowed the plaintiff's hostile work environment claim to proceed, citing, as a reason, Mr. Torchia's expert report that outlined deficiencies in the defendant's investigation. Id. Later, the same court found that Mr. Torchia “[m]ay opine relying upon alleged deviations from cited nonlegal standards in conducting workplace investigations necessary to refute the affirmative defense of acting reasonably and promptly to correct or prevent alleged discrimination.” Vandergrift v. City Of Phila., No. 16-2999, Ord. at 1, ECF No. 52. The Vandergrift court found that the proposed testimony identified deficiencies in the defendant's investigation, which are relevant to the determination of whether the defendant took adequate measures to address the plaintiff's allegations. Id. at 3-5. On the other hand, the court found that Mr. Torchia would not be permitted to testify about whether defendant's conduct violated applicable law. Id. at 7.

Similarly, in Barnes v. Shell Exploration and Prod. Co. Appalachia, the Middle District of Pennsylvania permitted Mr. Torchia to testify about the sufficiency of an investigation in a case involving supervisory harassment, but did not permit Mr. Torchia to testify about the relevant legal standards or caselaw. No. 18-1497, Ord. at 6-7, ECF No. 117.

Under these circumstances, Mr. Torchia will be permitted to submit an updated report, consistent with this opinion, that offers an opinion on the relevant industry standards for conducting a proper and appropriate investigation. As noted, Mr. Torchia may not include opinions on the relevant caselaw and legal standard. Additionally, Mr. Torchia's report may not offer an ultimate conclusion about whether Defendant's conduct violated the relevant industry standards.

B. Motion to Exclude Mr. Hailey's Past Criminal History

Plaintiff does not oppose Defendant's motion to exclude evidence of Mr. Hailey's criminal history so it will be granted as unopposed.

C. Motion to Exclude Evidence of Mr. Hailey's Past Workplace Conduct

[11] Defendant seeks to exclude evidence of prior written discipline that Mr. Hailey, Plaintiff's alleged assailant, had received during his employment with Defendant and Defendant's predecessor, Kennedy University Health System. Defendant argues that evidence relating to attendance issues, performance write-ups, absences, and issues related to Mr. Hailey not taking a patient's vital signs correctly are in no way relevant to the acts Mr. Hailey is accused of committing in this case.

*5 [12] Defendant argues that such evidence is inadmissible pursuant to [Federal Rule of Evidence 404](#) as it is evidence of a past act that is "not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." [Fed. R. Evid. 404\(b\)\(1\)](#). To be admissible under [Rule 404\(b\)](#):

- (1) The evidence must have a proper purpose under [Rule 404\(b\)](#); (2) it must be relevant under Rule 402;
- (3) its probative value must outweigh the prejudicial effect under Rule 403; and (4) the [district] court must charge the jury to consider the evidence only for the limited purpose for which it was admitted.

[Becker v. ARCO Chem. Co.](#), 207 F.3d 176, 189 (3d Cir. 2000) (citing [J & R Ice Cream Corp. v. Cal. Smoothie Licensing Corp.](#), 31 F.3d 1259, 1268 (3d Cir. 1994)).

[13] [14] With respect to the first prong, evidence must be relevant to a non-propensity purpose to be admissible. [United States v. Repak](#), 852 F.3d 230, 243 (3d Cir. 2017). When a proponent contends that the evidence "is both relevant and admissible for a proper purpose, 'the proponent must clearly articulate how that evidence fits into a chain of logical inferences, no link of which may be the inference that the defendant has the propensity to commit the crime charged.' " [Becker](#), 207 F.3d at 191 (citing [United States v. Morley](#), 199 F.3d 129, 133 (3d Cir. 1999)). Defendant argues that there is no non-propensity purpose for which this evidence can be admitted. In response, Plaintiff argues that this evidence pertains to Mr. Hailey's overall credibility because a member of Defendant's human resources department previously testified during her deposition that Mr. Hailey would bend the rules to "would work the rules in his favor." Berwick Dep. 45:18-46:5, ECF No. 52-7. Plaintiff seeks to introduce such evidence and testimony at trial.

The Court does not find that Plaintiff has shown how this "evidence fits into a chain of logical inferences." [Becker](#), 207 F.3d at 191. Plaintiff clearly seeks to use this evidence to show that because Mr. Hailey has allegedly broken the rules in the past, he was likely to do so with respect to Plaintiff. The Court finds that Plaintiff does not seek to offer this evidence for a proper purpose that is admissible under [Rule 404\(b\)](#).¹ Accordingly, Defendant's motion will be granted on this ground.

D. Motion to Exclude Evidence of a Prior Incident Relating to Alleged Sexual Misconduct

[15] During the course of Defendant's investigation, a human resources representative found a somewhat illegible handwritten incident report dated May 26, 2008 and a related corrective action notice in Mr. Hailey's department file. The incident report

appears to involve a prior allegation of assault against Mr. Hailey by a patient. Defendant anticipates that Plaintiff will seek to introduce these documents as evidence of a prior incident of harassment that human resources personnel should have questioned Mr. Hailey about during the investigation. Plaintiff argues that this evidence is relevant of whether Defendant took “prompt and appropriate remedial action” when conducting its investigation. [Huston](#), 568 F.3d at 104.

*6 Defendant argues that admitting such evidence would violate [Federal Rules of Evidence 403](#) as it would be more prejudicial than probative to allow such evidence to be admitted. See [Fed. R. Evid. 403](#) (“The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of ... unfair prejudice”). Defendant argues that the jury may assume that Mr. Hailey engaged in an unwanted sexual act with a patient even though the incident report is otherwise illegible. The related corrective action notice also does not include any details other than a note that Defendant was suspended.

Because the incident report is more than a decade old, is somewhat illegible, and does not clearly describe what Mr. Hailey was accused of, the Court finds that, pursuant to [Rule 403](#), the danger of unfair prejudice of introducing the incident report and related corrective action notice would substantially outweigh any probative value such evidence may have. Accordingly, the Court will grant Defendant's motion on this ground.

E. Defendant's Motion to Exclude Evidence Regarding Comments Mr. Hailey Made to Mary Pentz

[16] [17] After Plaintiff reported Mr. Hailey for allegedly assaulting her, Plaintiff informed Defendant that she allegedly found a note written by Mr. Hailey in her vehicle. Defendant investigated this claim. During the course of Defendant's investigation into the origin of the note, Defendant's human resources personnel interviewed another employee, Mary Pentz. Following the interview, Lakisha Reddick, a staff member in Defendant's human resources department, sent an e-mail recapping her interview with Ms. Pentz to her supervisor, Julie Ellis. Ms. Ellis made the final determination about Plaintiff's allegations. However, Ms. Ellis never followed up with or otherwise acknowledged Ms. Reddick's e-mail. The e-mail provides:

Mary stated that ‘[Mr. Hailey] was always creepy and had made a comments [sic] to her that he would ‘teach her to love him they [sic] way he loved her’. Mary felt that was just bizarre since she did not know where those comments came from. According to Mary this comment was at least 15 years ago and there had been no recent incidents with Anthony. Mary stated that Anthony was always friendly.

Def. Mot. at 29, ECF No. 70-1.

Defendant argues that the contents of the e-mail are hearsay as Plaintiff would offer them for the truth of the matter. In response, Plaintiff avers that Mr. Hailey's statements, Ms. Pentz's statements, and the e-mail itself are not being offered for the truth of the matter. Instead, Plaintiff seeks to use the e-mail to show that Ms. Reddick e-mailed the report to her supervisor, Ms. Ellis, and Ms. Ellis never followed up with or otherwise acknowledged the e-mail. Because, as noted, a central issue in this case is whether Defendant's human resources department conducted an “investigation ... in a way that prevent[ed] the discovery of serious and significant harassment by an employee such that the remedy chosen by the employer could not be held to be reasonably calculated to prevent the harassment,” Plaintiff argues that this is probative of whether Ms. Ellis conducted a proper investigation before making a decision in this case. [Knabe](#), 114 F.3d at 414.

At the hearing, Defendant argued that allowing Plaintiff to introduce the e-mail for this limited purpose would increase the likelihood of confusing the relevant issues under [Federal Rule of Evidence 403](#). The Court does not find that the probative value of whether Ms. Ellis conducted a proper investigation is substantially outweighed by the danger of confusing the issues. In any case, a limiting instruction will cure any danger of confusion.

*7 Accordingly, Plaintiff may not offer the e-mail for the truth of the matter, but may use the e-mail for the limited purpose of supporting the argument that Ms. Ellis failed to consider the material information provided by her staff members. If Plaintiff chooses to offer this evidence, the Court will give a limiting instruction to that effect.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion will be granted in part and denied in part. An appropriate order follows.

All Citations

--- F.Supp.3d ----, 2022 WL 334169, 117 Fed. R. Evid. Serv. 1216

Footnotes

- 1 Pursuant to [Federal Rule of Evidence 404\(b\)\(2\)](#), evidence of another wrong or act “may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.”

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United States District Court,
M.D. Pennsylvania.

John BARTOLI, Plaintiff

v.

NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.

Civil Action No. 3:13-0724.

I

Signed April 17, 2014.

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MEMORANDUM

MALACH E. MANNION, District Judge.

*1 Pending before the court are defendant Novartis Pharmaceuticals Corporation's ("NPC") motions, brought pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) and Federal Rule of Evidence 702, to exclude the expert testimony of Dr. Keith Stubitz, (Doc. 183), Dr. Robert Marx, (Doc. 185), Dr. Suzanne Parisian, (Doc. 187), Professor Wayne Ray, (Doc. 189), and Dr. James Vogel, (Doc. 191).

Throughout the country, cancer patients who have been treated with two of NPC's drugs, and who have afterwards developed osteonecrosis of the jaw, a debilitating and painful disease in which the jaw bone becomes exposed, have sued in products liability actions. In each of these cases, NPC has objected to the testimony of plaintiff's experts on varying grounds. The courts have agreed with NPC's objections to varying degrees, generally allowing the experts to testify while limiting the testimony in specific respects. This court follows the same course.

I. BACKGROUND

Aredia® and Zometa® are two FDA-approved drugs, called intravenous bisphosphonates ("BP"), manufactured by Novartis. The drugs are administered for treatment of advanced cancers which affect the bones. Plaintiff John Bartoli was treated with Aredia® and Zometa® for multiple myeloma.¹ He alleges that as a result of using the BP drugs, he developed osteonecrosis² of the jaw (ONJ).

This case is a pharmaceutical products liability action in which plaintiff brings claims for strict products liability, negligence, and breach of warranty. (Doc. 1). The case was transferred here from the Eastern District of New York on March 19, 2013. (Doc. 58). Before the transfer, the case was part of the Aredia® and Zometa® products liability multi-district litigation ("MDL") in the Middle District of Tennessee for pre-trial purposes. (MDL No. 1760).

Several litigation-wide experts, whose testimony is at issue here, were retained by the various plaintiffs whose cases were consolidated in the MDL. NPC challenged their testimony during the MDL and continues to challenge the testimony in all of the MDL cases which have been remanded for trial to various districts across the country.

II. LEGAL STANDARD

The admissibility of expert testimony is governed by [Federal Rule of Evidence 702](#), which requires an expert witness to have “specialized knowledge” regarding the area of testimony. The Third Circuit has explained, “The basis of this specialized knowledge can be practical experience as well as academic training and credentials,” and “[w]e have interpreted the specialized knowledge requirement liberally.” *Betterbox Commc’ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 327–28 (3d Cir.2002) (internal citations omitted). The Federal Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact. *Id.* Moreover, [Rule 702](#) “has a liberal policy of admissibility.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 806 (3d Cir.1997).

*2 When faced with a proffer of expert testimony, the court must determine “whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” *Daubert*, 509 U.S., at 592. The *Daubert* court held that the Federal Rules of Evidence “assign to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *Id.*, at 597. The test of reliability is “flexible,” and *Daubert*’s list of specific factors—testing, peer review, error rates, and “acceptability” in the relevant scientific community—neither necessarily nor exclusively applies to all experts or in every case. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

In performing its gatekeeping function to determine whether an expert’s report is relevant and reliable under *Daubert* and [Rule 702](#), “the court is not to weigh the evidence relied upon or determine whether it agrees with the conclusions reached therein.... Determinations regarding the weight to be accorded, and the sufficiency of, the evidence relied upon by the proffered expert are within the sole province of the jury.” *Walker v. Gordon*, 46 F. App’x 691, 695 (3d Cir.2002) (citing *Breidort v. Sears, Roebuck & Co.*, 722 F.2d 1134, 1138–39 (3d Cir.1983) (“Where there is a logical basis for an expert’s opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.”)).

III. DISCUSSION

The court will address each disputed expert separately. Defendant’s motions contain requests for *Daubert* hearings. The court finds that these issues have been litigated in case after case throughout the country, and does not believe that, with the abundance of case law addressing the specific questions at issue here, *Daubert* hearings are necessary. Because these experts’ qualifications have been repeatedly discussed and accepted by various courts around the country, the court will not address in depth the education, background, and experience of the various experts in question, except insofar as it is necessary to decide the motions at issue.

1. Dr. Keith Skubitz

At the MDL stage of these proceedings, Judge Campbell ruled that “the testimony of Dr. Skubitz concerning general causation and the scientific and medical accuracy of the warnings given by Novartis is clearly more than unsupported speculation,” and that, “Dr. Skubitz’s testimony concerning general causation and the accuracy of the warnings is admissible under *Daubert*.” (Doc. 151). NPC’s instant motion does not address testimony on those matters, but seeks to exclude Dr. Skubitz’s opinions regarding: 1) alternative BP dosing; 2) pre-BP-therapy dental screening, and; 3) the incidence of ONJ in patients treated with *Aredia*® and *Zometa*®. Judge Campbell declined to rule on these specific issues in the MDL, deeming them moot because they did not apply to the summary judgment motion pending before him at the time³. (Doc. 151).

*3 First, as to the issue of alternative dosing schemes, NPC argues that Dr. Skubitz relies on an unreliable study to opine that less frequent dosing of the drugs in question is beneficial in preventing ONJ. Novartis objects to Dr. Skubitz’s reliance on this

“Corso” study because it is a retrospective observational study without a control group. The court finds that the objections as to the Corso study go more to the weight of the Dr. Skubitz's testimony than its admissibility. The litigation and documents from the MDL and related cases have recognized that if a non-controlled observational study has been peer-reviewed and accepted for publication in a scientific journal, that is a good indication that it has been “taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.” *Deutsch v. Novartis Pharm. Corp.*, 768 F.Supp.2d 420, 446 (E.D.N.Y.2011). Dr. Skubitz may opine on alternative dosing as it relates to opinions based on the Corso study.

Defendant also argues that Dr. Skubitz's opinion that reduced dosing has led to decreased incidence of ONJ in his own patients is without methodological support and is prohibited *ipse dixit* testimony. The court agrees. There is nothing in Dr. Skubitz's rebuttal report, (Doc. 184–5), to suggest a scientific methodology which led him to the conclusion that alternative dosing regimens have led to a lower incidence of ONJ in his patients. Thus, this opinion is *ipse dixit*, and Daubert and Rule 702 do not permit him to offer opinions based on his observation of his own patients.

Second, defendant argues that Dr. Skubitz's opinion regarding the benefits of pre-BP-therapy dental evaluations does not satisfy Daubert's “fit” requirement, contending that there is no evidence that a warning to seek such therapy would have prevented Mr. Bartoli's jaw issues and that Mr. Bartoli had a dental examination seven months before starting BP treatment.⁴ The “fit” requirement “goes primarily to relevance.” *Furlan v. Schindler Elevator Corp.*, 864 F.Supp.2d 291, 296 (E.D.Pa.2012) (citing *Daubert*, 509 U.S., at 591). Not knowing the exact circumstances of that visit, and without more than a glancing reference to that visit by defendants, the court cannot say that the dental visit was substantially similar to the type of pre-therapy screening Dr. Skubitz recommends, or that the visit makes the screening testimony irrelevant. As to defendant's argument that the opinion is speculative and based on retrospective research, the court refers to its above discussion of retrospective studies. Dr. Skubitz may testify as to pre-therapy dental screening.

Finally, defendant argues that Dr. Skubitz should not be allowed to testify to incidence rates of ONJ in those undergoing BP treatment. Defendant again rests this argument on the unreliability of the underlying studies on which Dr. Skubitz relies. The methodology of the underlying studies is a matter for cross-examination, but does not preclude the testimony. *Deutsch*, 768 F.Supp.2d, at 431.

*4 Accordingly, defendant's motion to exclude Dr. Skubitz's testimony, (Doc. 183), is **GRANTED IN PART AND DENIED IN PART**. Dr. Skubitz may testify as to his opinions regarding the benefits of alternative dosing, the benefits of pre-therapy dental screening, and incidence of ONJ, and defendant's motion is **DENIED** as to those topics. Dr. Skubitz may not, however, testify as to his observations regarding the incidence of ONJ after he reduced dosing in his own patients, and defendant's motion is **GRANTED** as to that issue.

2. Dr. Robert Marx

At the MDL stage of these proceedings, defendant moved to exclude Dr. Marx's testimony regarding “(1) the causal connection between Aredia and Zometa and ONJ, (2) treatment and preventative measures for ONJ, (3) alleged misconduct by NPC which he considers to be taken in “bad faith,” (4) whether certain patients in the Aredia/Zometa clinical trials likely had BP-induced ONJ, and (5) criticisms of certain aspects of the clinical trials.” (Doc. 154). Judge Campbell ruled that for purposes of summary judgment, Dr. Marx's testimony was admissible, with the exception of “opinions concerning the alleged “bad faith” misconduct of Novartis or his opinions concerning the clinical trials,” which Judge Campbell deemed moot, as he did not need to consider those aspects of the testimony for summary judgment purposes. (*Id.*).

Defendant's current motion seeks to exclude Dr. Marx from: (1) testifying that dental treatment measures prevent ONJ; (2) presenting his opinion that NPC engaged in “bad faith” conduct; (3) criticizing the clinical trials; (4) speculating that certain patients in the clinical trials for Zometa® and Aredia® had ONJ; (5) presenting general causation opinions based on adverse event reports; and (6) testifying about the biological mechanism by which BPs allegedly cause ONJ.

First, as to the biological mechanism by which BPs cause ONJ, the court finds that the MDL order already decided this exact issue, which was presented to the MDL Court.

“However, even if the MDL court's decision was not binding, the Court would still find that Dr. Marx is more than qualified to testify with regard to this theory. Dr. Marx has conducted research, published peer-reviewed articles, and essentially served as an authority on the relationship between bisphosphonates and ONJ. The Court has no doubt that his academic involvement and extensive background in identifying, treating, and studying patients with ONJ qualifies him to render opinions on this subject.”

Deutsch, 768 F.Supp.2d, at 438–39; see also Doc. 154.

Second, as to general causation opinions based on adverse event reports which Dr. Marx has not reviewed, the MDL court ruled on this very issue, and it is law of the case that Dr. Marx may testify as to general causation based on adverse events reports whether he has reviewed them or not. See *id.*, at 450–51.

Third, as to dental treatment measures to prevent ONJ, NPC presents the same arguments as it employed in attempting to keep Dr. Skubitz from testifying on preventative dental screenings. For the same reasons as above, the court will allow Dr. Marx to opine on preventative dental screenings.

*5 Fourth, as to whether Dr. Marx may testify as to NPC's bad faith, plaintiff argues that NPC attempted to control the conclusions of advisory boards it convened, in which Dr. Marx was personally involved, that no specialized knowledge is needed for Dr. Marx to testify about bad faith, and that he can testify to his perception of NPC's actions as they relate to how he felt NPC was dealing with him. However, “intent is not a proper subject for expert testimony” and “expert testimony that constitutes a legal opinion is inadmissible.” *Wolfe v. McNeil-PPC, Inc.*, 881 F.Supp.2d 650, 661–62 (E.D.Pa.2012). While Dr. Marx may testify as a fact witness about his experience working with NPC and its employees, and he may offer opinion as to what information about ONJ was available to NPC in light of the medical literature and NPC internal documents, he may not opine on whether NPC acted in good faith or otherwise opine as to NPC's intent or motivations. See *Deutsch*, 768 F.Supp.2d, at 448.

Fifth, as to Dr. Marx's opinion that patients in the clinical trials were suffering from ONJ, NPC informed the FDA in 2005 that a retrospective review of its data from the clinical trials for the BP drugs had identified six individuals whose symptoms were “consistent with a *potential* diagnosis of ONJ.” (Doc. 186). Dr. Marx, rebutting the report of NPC's expert that none of the six likely suffered from ONJ, opined that five of the six likely suffered from ONJ.(Doc. 186–3). NPC argues that Dr. Marx did not apply his own definition of ONJ in making these findings, namely, that he found the likelihood of ONJ even where the records did not reflect the presence of exposed bone, and that this lack of methodological soundness should preclude him from testifying as to this opinion.

The court agrees that Dr. Marx did not employ his own methodology, but finds that this was because the records from the clinical trials were created before there was any definition of ONJ induced by BP drugs, and so the records would not necessarily reflect the presence of exposed bone. See *Deutsch*, 768 F.Supp.2d, at 449–50. Thus, it was reasonable for Dr. Marx to look for circumstantial evidence supporting ONJ in the incomplete records. NPC is free to cross-examine Dr. Marx about the accuracy of his opinion based on the records, but he will be allowed to give an opinion on the topic.

Finally, NPC seeks to exclude Dr. Marx's opinion criticizing NPC's clinical trials for the drugs in question. Dr. Marx states that “[a]s a research matter, I found the records to be a serious deviation of proper research data recording and noted that jaw and mouth examinations were apparently not routinely performed as part of the trial.” (Doc. 186–3). NPC argues that this is inadmissible because Dr. Marx admitted that he used “20/20 hindsight,” not a reliable scientific methodology, in reaching this opinion, and that Dr. Marx is not qualified to opine on the adequacy of the trials because he had admitted that he has not “planned

or managed any clinical trials” related to BP drugs, or any clinical drug trials. The court finds that Dr. Marx is not qualified to opine on the adequacy of the clinical trials. He can testify as to what information was not included in records, or that oral examinations were not performed, but he may not opine that such information or examinations should have been performed. See *Deutsch*, 768 F.Supp.2d, at 450.

*6 Accordingly, defendant's motion to exclude Dr. Marx's testimony, (Doc. 185), is **GRANTED IN PART AND DENIED IN PART**. Dr. Marx may testify as to preventative dental screenings, his opinion that some of the clinical trial patients had ONJ, general causation opinions based on adverse event reports, and the biological mechanism by which BPs allegedly cause ONJ. Dr. Marx may not testify as to whether NPC engaged in “bad faith” conduct, and he may not criticize the adequacy of the clinical trials.

3. Dr. Suzanne Parisian

NPC moves to exclude aspects of the testimony of Dr. Suzanne Parisian, (Doc. 187), specifically: 1) opinions regarding regulatory compliance; 2) the adequacy of the labeling of *Aredia*® and *Zometa*®; 3) any opinions regarding causation; 4) testimony regarding NPC's use of a ghostwriter, undisclosed company funding of publications, and ethical standards a reasonable pharmaceutical company should follow, and; 5) opinions about NPC's intent.

As an initial matter, Dr. Parisian has repeatedly served as a trial expert on the matters at issue here, and has significant expertise with the FDA and its practices, something about which the average layperson does not have significant knowledge. Generally, she is qualified to testify. See *Lemons v. Novartis Pharmaceuticals Corp.*, 849 F.Supp.2d 608, 613 (W.D.N.C.2012) (collecting cases in which Dr. Parisian has been permitted to testify).

As to NPC's specific objections, first, Dr. Parisian may not testify as to NPC's intent, motive, or bad faith. As discussed above, “intent is not a proper subject for expert testimony.” *Wolfe*, 881 F.Supp.2d, at 661. Similarly, “bad company” opinions are not admissible. *Deutsch*, 768 F.Supp.2d, at 467 (citing *In re Trasylol Products Liability Litigation*, 709 F.Supp.2d 1323, 1337–38 (S.D.Fla.2010)).

Second, as to pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, Dr. Parisian may not testify. There is nothing to suggest that she is an expert in pharmaceutical company ethics-she has never worked at a pharmaceutical company, and ethical standards for such companies do not come from the FDA, which is the agency about whose operations Dr. Parisian has expertise. Likewise, her testimony regarding ghostwriting and undisclosed company funding is inadmissible because she opines, without foundation, that employing such practices does not provide “fair and balanced” information and that it must be disclosed. See *Deutsch*, 768 F.Supp.2d, at 468; see also *Lemons*, 849 F.Supp.2d, at 615.

Third, as to causation, Dr. Parisian may not testify. Dr. Parisian is not an expert in ONJ, and does not currently treat patients. Plaintiff admits as much. (Doc. 195, Ex. A, at 9). Dr. Parisian is not qualified to give causation evidence of any kind. *Forman v. Novartis Pharmaceuticals Corp.*, 794 F.Supp.2d 382, 384 (E.D.N.Y.2011) (citing *Deutsch*, 768 F.Supp.2d, at 465).

*7 Finally, Dr. Parisian may testify as to the FDA regulatory scheme and the role of the FDA and its interactions with pharmaceutical companies. NPC objects to the methodology she employed in reaching her conclusions, and her opinions in this area have been accepted by courts again and again, and her expertise in the complicated field of pharmaceutical regulation can surely be of use to a jury. *Id.* (collecting cases admitting Dr. Parisian's testimony on this subject). Furthermore, the *Forman* court determined, after a two-day Daubert hearing, that Dr. Parisian's methodology for forming her opinions regarding NPC's interactions with the FDA consisted of

“her review of certain NPC regulatory filings, internal NPC documents, and medical literature. Furthermore, as Dr. Parisian testified, she reached the opinions expressed in her report by taking this

information and applying the relevant FDA regulations and procedures. As her testimony at the hearing clarified, this is the same methodology that she applied while working at the FDA.”

Forman, 794 F.Supp.2d, at 384.

The court thus determined that Dr. Parisian could testify regarding “the reasonableness of Novartis' conduct in its interactions with the FDA and compliance with FDA regulations, including Novartis' interactions with FDA with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials.” *Id*; see also *Lemons*, 849 F.Supp.2d, at 615 (finding that Dr. Parisian's proposed testimony as to labeling is “reasoned, based on the context of the warnings, the content of the warnings, and on the consideration of the alternative language”). This court agrees, and will allow Dr. Parisian to testify on those matters.

Accordingly, defendant's motion to exclude the testimony of Dr. Suzanne Parisian, (Doc. 187), is **GRANTED IN PART AND DENIED IN PART**. Dr. Parisian may not testify as to NPC's intent, pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, or causation. Dr. Parisian may testify as to regulatory compliance and the reasonableness of NPC's conduct in its interactions with the FDA and compliance with FDA regulations, including NPC's interactions with FDA with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials.

4. Professor Wayne Ray

Defendant moves to exclude the testimony of Prof. Wayne Ray. (Doc. 189). Specifically, NPC seeks to exclude: 1) Prof. Ray's meta-analyses; 2) testimony that it is biologically plausible that BP drugs increase the risk of ONJ; 3) testimony that a causation opinion regarding ONJ could have been reached in 2003, and; 4) testimony regarding the incidence of ONJ in BP patients and testimony that ONJ is not “rare.”

Professor Ray is an epidemiologist, Professor of preventative medicine, director of the division of pharmacoepidemiology and director of the master of public health program at Vanderbilt University School of Medicine. He has significant experience in evaluating and designing studies to determine whether there is evidence that a medication causes bad reactions. He gives advice and does studies on adverse medication reactions and assesses whether medication use is appropriate. (Doc. 190–5).

*8 First, NPC objects to the use of the meta-analyses employed by Prof. Ray. A meta-analysis combines the results of several studies to increase precision and reduce the likelihood that any association found by the studies is due to sampling error. *Deutsch*, 768 F.Supp.2d, at 452 (citing Reference Manual on Scientific Evidence, Fed.Jud.Ctr.2d ed.2000). “Meta-analysis is best suited to pooling the results from randomly-controlled experimental studies, but if carefully performed, it is also useful for observational studies.” *Id*. While meta-analyses can be easily misunderstood or used in circumstances where they should not be used, that does not mean they are necessarily unreliable. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 857–58 (3d Cir.1990).

Here, Prof. Ray performed two meta-analyses. The first (the “Table 5 study”) addresses the relative risk of developing ONJ while using BPs. NPC argues that Prof. Ray failed to account for some confounding factors, that he used the patients as their own control groups, and that he treated BPs users who had been undergoing the treatment for 3 months or less as though they had not undergone BP therapy at all. However, Prof. Ray's report and his deposition testimony show that he has outlined the basis for the Table 5 study, addressed its potential flaws, and shown the methodology he employed and how he arrived at it. Moreover, he submitted a rebuttal report responding to many of NPC's complaints about his methodology. As someone with extensive experience in assessing epidemiological studies, Prof. Ray is qualified to conduct this analysis. This meta-analysis cannot be considered impermissible speculation. The court will allow Prof. Ray to testify about his Table 5 study. See *Deutsch*, 768 F.Supp.2d, at 456–57.

Prof. Ray also performed a meta-analysis (the “Table 6 study”) regarding the increased risk of developing ONJ while taking Zometa® as compared to Aredia®. NPC also objects to the reliability of the methodology of this study. Here, Prof. Ray did not employ the same reliable methodology as with the Table 5 study, failing to account for duration of therapy as it relates to increased risk, a factor which he had determined was an important one in evaluating the risk of contracting ONJ. Having concluded that duration was important, he cannot reasonably have failed to account for it in his subsequent study. Prof. Ray may not, therefore, testify as to the Table 6 study. *See id.*, at 458.

Second, NPC objects to Prof. Ray's opinion that it is biologically plausible that BP drugs increase the risk of ONJ on the grounds that he is not a medical doctor, does not prescribe BP drugs, and that he has not posited a particular biological mechanism of causation. The court disagrees. Where a “hypothesis has been deemed plausible and credible in the relevant medical literature” and where it is within an expert's “field of expertise based on training, experience, and history of publication,” it is reasonable to admit that hypothesis. *In re Pfizer Inc. Sec. Litig.*, 2010 WL 1047618, at *6 (S.D.N.Y. Mar.22, 2010). Prof. Ray may give an opinion regarding biological plausibility.

*9 Third, NPC objects to an opinion that a causation conclusion regarding BPs and ONJ could have been reached in 2003. NPC argues that causation has not yet been definitively proven and that the evidence Prof. Ray relies on in his analysis was not available prior to 2003. Prof. Ray bases this conclusion on Dr. Marx's report and an increase in reports of ONJ in BP users for which he does not think there is an alternate explanation. While this may not be the strongest factual basis for an opinion, that is a matter of weight, and not admissibility. Dr. Ray may testify as to whether a conclusion could have been reached in 2003.

Finally, NPC moves to exclude Prof. Ray's testimony regarding incidence of ONJ and his statement that ONJ is not “rare” in BP patients. NPC argues that Dr. Ray relied on studies that were not controlled and randomized to reach that conclusion. As the court found in the discussion of uncontrolled studies above, that is a matter of weight, and not admissibility. Dr. Ray may opine as to incidence rate. He may not, however, testify that the incidence rate correlates to ONJ being not “rare” among BP patients. Plaintiff does not present an argument about why the term is appropriate, and the court finds that the term is undefined and could be misleading. *See Deutsch*, 768 F.Supp.2d, at 459.

Accordingly, defendant's motion to exclude Prof. Ray, (Doc. 189), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to the Table 6 meta-analysis and the use of the word “rare” in relation to the incidence rate. Defendant's motion is **DENIED** as to the Table 5 meta-analysis, the biological plausibility that BPs cause ONJ, that a causation determination could have been reached in 2003, and an opinion that the incidence rate of ONJ in BP users is 5%.

5. Dr. James Vogel

At the MDL stage of these proceedings, NPC argued that Dr. Vogel was not qualified to give any of his opinions. (Doc. 152). Judge Campbell found Dr. Vogel qualified, and admitted testimony regarding “general causation and the scientific and medical accuracy of the warnings given by Novartis.” (*Id.*). The MDL court did not consider his opinions regarding “the alleged corporate behavior of Novartis, his statement that the delay and failure in transmission of certain information impacted a large number of patients, or his testimony concerning the benefit of pretreatment dental screening.” (*Id.*). The court thus deemed those portions of the motion moot. (*Id.*).

Presently, defendant moves to exclude the testimony of Dr. James Vogel. (Doc. 191). Specifically, defendant wished to exclude opinions regarding: 1) NPC's corporate conduct; 2) pre-BP treatment dental screenings; 3) incidence of ONJ; 4) alternative BP dosing regimens, and; 5) biological mechanism by which BPs affect jaw bones.

Dr. Vogel has been a hematologist and medical oncologist for 35 years. He sees patients regularly, and sees patients with both “solid tumors,” as well as blood cancers such as multiple myeloma. He is as Associate Professor of hematology and medical oncology at the Mount Sinai School of Medicine. He prescribes BP drugs to his patients.

*10 First, as to testimony about NPC's corporate conduct, NPC argues that Dr. Vogel lacks any firsthand knowledge and formed his opinions from internal NPC documents presented to him during litigation. They allege that Dr. Vogel cannot testify:

(1) that NPC misrepresented causation evidence; (2) that NPC referenced corticosteroids as potential risk factors for ONJ in the warnings on its label to misdirect “the focus of medical attention away from the jaw area”; (3) that NPC minimized the incidence rate of ONJ; (4) that ONJ occurs in a patient after fewer infusions of Zometa® than of Aredia® and/or that NPC knew and failed to communicate that information; and (5) that a decrease in the duration and/or dosing frequency of therapy decreases the incidence of ONJ or that NPC knew and failed to communicate that information.

As noted above, an expert may not opine as to the intent or motive of NPC. To the extent that Dr. Vogel's testimony seeks to do this, it will not be allowed. However,

“Dr. Vogel can opine on the medicine and science that was available at the time regarding the risks and benefits of Aredia and Zometa, and can compare that information to what was disclosed on the label or in other materials Novartis presented to the medical community. To the extent the information on the known risks is derived from internal Novartis documents, Dr. Vogel's scientific expertise is helpful to the trier of fact in understanding those documents.”

Deutsch, 768 F.Supp.2d, at 443.

Second, in accordance with the court's above rulings regarding the testimony of Dr. Marx and Dr. Skubitz on the same topic, Dr. Vogel will be permitted to testify as to the benefits of pre-treatment dental screenings.

Third, as to opinions regarding the incidence rate of ONJ in BP patients, the court has addressed this issue in discussing Dr. Skubitz and Dr. Marx. For the same reasons, the court finds that NPC's objections regarding the reliability of the underlying studies and Dr. Vogel's failure to consider studies published after his initial report go to the weight of the evidence, not to its admissibility. Dr. Vogel may testify as to incidence rate of ONJ in BP patients.

Fourth, NPC objects to Dr. Vogel's opinions regarding an alternative dosing schedule because he relies on the same Corso report as Dr. Marx, and he lacks expertise regarding FDA labeling. First, the court noted above that reliance on the Corso study is permissible. As to whether he is qualified to opine on the dosing information that NPC should have provided to the medical community, the MDL court ruled that Dr. Vogel may testify as to whether the label dosing information was false or misleading. Thus, Dr. Vogel may testify as to alternative BP dosing regimens.

Finally, as to whether Dr. Vogel may opine about the biological mechanism by which BPs affect jawbones, NPC contends that Dr. Vogel is not qualified to opine because he is not a bone pathologist or bone biologist. “While the MDL court did find that Dr. Vogel's inability to explain the mechanism did not render his opinions unreliable as to the biological mechanism generally, the MDL court did not directly address whether Dr. Vogel is qualified to offer an opinion on the particular hypothesis about bisphosphonates targeting the bone.” *Id.*, at 439. This court finds that Dr. Vogel is qualified to testify on the matter. While he admits that he is not an expert in bone pathology, he is an expert in **cancers of the blood**, a closely related field at the heart of this case. “Rule 702's liberal policy of admissibility extends to the substantive as well as the formal qualification of experts. We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications.” *Paoli, 35 F.3d, at 741*. Furthermore, Dr. Vogel is not offering his opinion as the mechanism, but rather indicating that it is a plausible one given his understanding of the relevant medical literature. *Deutsch, 768 F.Supp.2d, at 439*. Dr. Vogel may testify as to the biological mechanism.

*11 Accordingly, defendant's motion to exclude the testimony of Dr. Vogel, (Doc. 191), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** to the extent that Dr. Vogel may not opine as to the intent or motive of NPC. Defendant's motion is **DENIED** as to testimony regarding pre-dental screenings, incidence rate of ONJ in patients, alternative BP dosing regimens, and the biological mechanism by which BPs affect the jaw bone.

IV. CONCLUSION

For the foregoing reasons, each of defendant's motions, (Doc. 183, Doc. 185, Doc. 187, Doc. 189, Doc. 191), is **GRANTED IN PART AND DENIED IN PART**. A separate order shall issue.

ORDER

In light of the memorandum issued this same day, **IT IS HEREBY ORDERED THAT:**

(1) Defendant's motion to exclude the testimony of Dr. Skubitz, (Doc. 183), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to Dr. Skubitz's observations regarding the incidence of ONJ in his own patients after he implemented a reduced dosing regimen, and **DENIED** as to testimony regarding the benefits of alternative dosing, the benefits of pre-therapy dental screening, and incidence of ONJ;

(2) Defendant's motion to exclude the testimony of Dr. Marx, (Doc. 185), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to testimony regarding whether NPC engaged in "bad faith" conduct, and the adequacy of the clinical trials. Defendant's motion is **DENIED** as to opinions on preventative dental screenings, the opinion that some of the clinical trial patients had ONJ, general causation opinions based on adverse event reports, and opinion of the biological mechanism by which BPs allegedly cause ONJ;

(3) Defendant's motion to exclude the testimony of Dr. Suzanne Parisian, (Doc. 187), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to testimony of NPC's intent, pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, and causation. Defendant's motion is **DENIED** as to opinions regarding regulatory compliance and the reasonableness of NPC's conduct in its interactions with the FDA and compliance with FDA regulations;

(4) Defendant's motion to exclude the testimony of Prof. Wayne Ray, (Doc. 189), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to the Table 6 meta-analysis and the use of the word "rare" in relation to the incidence rate. Defendant's motion is **DENIED** as to the Table 5 meta-analysis, the biological plausibility that BPs cause ONJ, the opinion that a causation determination could have been reached in 2003, and an opinion that the incidence rate of ONJ in BP users is 5%, and;

(5) Defendant's motion to exclude the testimony of Dr. James Vogel, (Doc. 191), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** to the extent that Dr. Vogel may not opine as to the intent or motive of NPC. Defendant's motion is **DENIED** as to testimony regarding pre-dental screenings, incidence rate of ONJ in patients, alternative BP dosing regimens, and the biological mechanism by which BPs affect the jaw bone.

All Citations

Not Reported in F.Supp.3d, 2014 WL 1515870

Footnotes

- 1 Multiple myeloma is a cancer formed by malignant plasma cells. Normal plasma cells are found in the bone marrow and are an important part of the immune system. When plasma cells become cancerous and grow out of control, they can produce a tumor called a plasmacytoma. These tumors generally develop in a bone, but they are also rarely found in other tissues. When there is more than one plasma cell tumor, it is called multiple myeloma. [http:// www.cancer.org/ cancer /multiplemyeloma/detailedguide/multiple-myel oma-what-is-multiple-myeloma](http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma).
- 2 Osteonecrosis, which is also called avascular necrosis or aseptic necrosis, is the death of bone cells due to decreased blood flow. It can lead to pain and collapse of areas of bone. [http://www . rheumatology.org/Practice/Clinical/Patients/ Diseases _And_ Con ditions/Osteonecrosis/](http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Osteonecrosis/).
- 3 Plaintiff has responded to defendant's motions in this case by incorporating his briefs from the MDL proceedings. These briefs cover more territory than the specific arguments defendants raise in this case, and do not specifically respond to defendant's instant arguments. While the court will consider the incorporated briefs in this case, it notes that Local Rule 7.8 specifically states that, "No brief may incorporate by reference all or any portion of any other brief." Moreover, the local rule also limits briefs to 15 pages, which the incorporated briefs in this matter far exceed. Plaintiff is reminded to comply with the Local Rules in any future filings with the court.
- 4 The court notes that plaintiff has not responded to this argument.

2013 WL 7208221

Only the Westlaw citation is currently available.

United States District Court,
W.D. Oklahoma.

Jessica WELLS, individually and as next friend of J.W., a minor, Plaintiffs,

v.

ALLERGAN, INC., Defendant.

No. CIV-12-973-C.

I

Feb. 4, 2013.

Attorneys and Law Firms

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ORDER

ROBIN J. CAUTHRON, District Judge.

1 Now before the Court is “Defendant Allergan, Inc.’s Motion to Exclude Expert Testimony of David A. Kessler, M.D.” (Dkt. No. 92). Defendant argues for the exclusion of Dr. Kessler’s testimony on the grounds that it offers impermissible legal conclusions, will not assist the trier of fact, is speculative, and is unfairly prejudicial. Defendant does not challenge Dr. Kessler’s qualification as an expert on FDA regulation of the pharmaceutical industry.

Federal Rule of Evidence 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion ... if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Thus, to be admissible under Rule 702, the witness must be qualified as an expert, the testimony must be reliable, and the testimony must be relevant, meaning it would assist the trier of fact. See *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir.2004) (noting testimony must be both reliable and relevant); see also *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). Defendant’s challenge centers on whether Dr. Kessler’s testimony would be helpful to the jury.

Defendant first asserts that Dr. Kessler will “usurp the role of the Court” by “instruct[ing] the jury on a litany of legal issues.” (Def.’s Br., Dkt. No. 92, at 6.) To the extent Allergan seeks to preclude Dr. Kessler from testifying about FDA regulatory requirements and procedures or offering his opinion as to Allergan’s compliance therewith, the motion is DENIED. Defendant is correct that the Tenth Circuit prohibits experts from testifying so as “to direct the jury’s understanding of the legal standards upon which their verdict must be based.” *Specht v. Jensen*, 853 F.2d 805, 810 (10th Cir.1988). However, in *Specht*, the court cautioned that it was drawing a narrow line and did not intend to “exclude all testimony regarding legal issues,” as “a witness may refer to the law in expressing an opinion without that reference rendering the testimony inadmissible.” *Id.* at 809. In this case, the Court disagrees with Allergan that Dr. Kessler’s testimony about FDA regulations would “usurp” the role of the trial judge because this case is “not governed by federal regulations but by state law theories of negligence and strict liability.” *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 191 n.16 (S.D.N.Y.2009). Dr. Kessler’s testimony is admissible to assist the lay jury in “ ‘understand[ing] the complex regulatory framework that informs the standard of care in the pharmaceutical industry.’ ” *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, Case No. 3:09–MD–02100–DRH, 2011 WL 6302287, at *12 (S.D.Ill.Dec. 16, 2011) (quoting *Fosamax*, 645 F.Supp. at 191). Dr. Kessler may *not* testify as to the elements of a strict liability or negligence claim under Oklahoma law but *may* testify as to the law governing FDA regulations, Allergan’s compliance with those regulations, and the relationship between FDA regulations and state tort liability. *See id.* at *11 (“The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies [sic] compliance with FDA regulations.”). Cross-examination and competing expert testimony will ensure that the jury carefully weighs Dr. Kessler’s testimony. In addition, the Court will instruct the jury that the Court, not Dr. Kessler or any other witness, will inform the jury of the law applicable to this case.

*2 Allergan also challenges Dr. Kessler’s testimony as having an improper basis. According to Defendant, Dr. Kessler’s expert opinion “amounts to mind-reading,” to the extent he “seeks to offer testimony about the knowledge, motivations, intent, state of mind, and purposes of Allergan, the FDA, and Dr. Wright.” (Def.’s Br. at 10–11.) The Court agrees with Defendant that “mind-reading is not the type of ‘specialized knowledge’ contemplated by Rule 702” and that Dr. Kessler cannot be permitted to speculate as to the intent or state of mind of Allergan, the FDA, or Dr. Wright. (*Id.*) However, although Dr. Kessler cannot testify as to intent, Dr. Kessler can testify about facts from which the jury can infer intent. *See, e.g., DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir.1998) (holding an engineer could testify *as an expert* “that reducing the padding saved a particular amount of money ... [and] that [the manufacturer’s] explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify *as an expert* that [the manufacturer] had a particular motive”). Thus, Defendant’s motion with respect to state of mind testimony is GRANTED IN PART and DENIED IN PART. If Defendant feels that Dr. Kessler has departed from an analysis of the facts and entered the realm of speculation during his testimony, Defendant may object at trial.

Finally, Defendant contends that Dr. Kessler “improperly assumes the role of Plaintiffs’ advocate and invades the province of the jury” by “ ‘regurgitat[ing] the evidence through various factual narratives.’ ” (Def.’s Br. at 13.) To the extent the facts relied upon by Dr. Kessler in forming his opinions are relevant and not cumulative, Dr. Kessler may include them in his testimony. However, Dr. Kessler may not “simply rehash [] otherwise admissible evidence about which he has no personal knowledge.” *Highland Capital Mgmt., L.P. v. Schneider*, 379 F.Supp.2d 461, 468–69 (S.D.N.Y.2005). An expert must do more than simply “constructing a factual narrative based upon record evidence” or “address[] ‘lay matters which a jury is capable of understanding and deciding without the expert’s help.’ ” *Id.* at 469 (quoting *In re Rezulin Products Liab. Litig.*, 309 F.Supp.2d 531 (S.D.N.Y.2004)). Thus, Defendant’s Motion is GRANTED IN PART and DENIED IN PART. Defendant may object at trial if Dr. Kessler appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.

Accordingly, for the reasons and to the extent stated above, “Defendant Allergan, Inc.’s Motion to Exclude Expert Testimony of David A. Kessler, M.D” (Dkt. No. 92) is hereby GRANTED IN PART and DENIED IN PART.

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2013 WL 7208221

Footnotes

- * Dr. Kessler earned a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School, worked on food and drug issues for the United States Senate, served as Commissioner of the FDA under both President George H.W. Bush and President Clinton, served as the dean of two medical schools, taught drug regulation, consulted with private firms about drug regulation and FDA procedures, and has written and published numerous books and articles about the regulation of drugs and other public health topics.

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2012 WL 1204081

Only the Westlaw citation is currently available.

United States District Court, D. Arizona.

Catherine JOHNSON, Plaintiff,

v.

WYETH LLC; Pfizer Inc., individually and as successor in interest
to Pharmacia & Upjohn Co.; Wyeth Pharmaceuticals, Defendants.

No. CV 10-02690-PHX-FJM.

|

April 11, 2012.

Attorneys and Law Firms

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ORDER

FREDERICK J. MARTONE, District Judge.

*1 The court has before it defendants' motion to exclude opinions of plaintiff's experts Drs. Parisian, Blume, and Austin (doc. 79), plaintiff's response (doc. 99), and defendants' reply (doc. 109). This action arises from plaintiff's ingestion of hormone replacement drugs Premarin and Provera between 1982 and 1998, which she alleges caused her to develop breast cancer.¹

I

To be admissible, expert testimony must "help the trier of fact to understand the evidence or to determine a fact in issue," must be "based on sufficient facts or data," must be "the product of reliable principles and methods," and must be "reliably applied ... to the facts of the case." *Fed.R.Evid.* 702. The testimony must go beyond "subjective belief or unsupported speculation" to be reliable. See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590, 113 S.Ct. 2786, 2795, 125 L.Ed.2d 469 (1993).

II

Defendants move to exclude Dr. Austin's failure to test opinions. Plaintiff stipulates that Dr. Austin's testimony will be limited to a discussion of evidence concerning the link between certain hormone replacement therapy ("HRT") drugs and cancer and the kinds of studies that can be performed on drugs, their risks, and the information that the studies can reveal. Defendants concede that their motion is moot with respect to Dr. Austin.

III

Next, defendants move to exclude Dr. Parisian and Dr. Blume's opinions that defendants failed to act as a reasonable pharmaceutical company by failing to perform additional tests on their HRT drugs. They argue that there are no objective standards that required defendants to perform additional testing. Without an objective standard to which to point, defendants contend that Dr. Parisian and Dr. Blume merely offer personal opinions that defendants acted unreasonably.

Dr. Parisian's 2007 report opines that defendants breached the standard of a "responsible United States pharmaceutical manufacturer" by not voluntarily conducting studies to investigate the risks of [breast cancer](#) and update their product warnings. *Mot.*, ex. 20 at 16. Similarly, Dr. Blume's report states that a "reasonable pharmaceutical company would have conducted a definitive study examining the [breast cancer](#) risk associated with hormone replacement and provided these results in the product labeling." *Id.*, ex. 21 at 29. Plaintiff was unable to point to anywhere in Dr. Blume's report or anywhere in Dr. Parisian's multiple reports that identify any FDA regulations or rules requiring defendants to test their HRT drugs after they were released on the market. By contrast, Dr. Parisian acknowledges that the "FDA was not given authority to require a company to perform safety studies for an already marketed drug." *Id.*, ex. 20 at 9.

Alternatively, plaintiff argues that the opinions are based on experience. While expert opinions can be based on personal experience, plaintiff has not pointed to any experience cited in the reports that the experts relied on in concluding that there is an objective standard of care for post-market testing. Indeed, both experts admitted that there is no set standard of care, because each company makes a subjective judgment as to the appropriate level of testing for its products. *See Mot.*, ex. 15, Parisian Dep. 571:15–572:8, July 20, 2007; *id.*, ex. 16, Blume Dep. 225:9–11, Apr. 7, 2006. Next, plaintiff argues that Drs. Parisian and Blume relied on defendants' admissions that they have a responsibility to make sure drugs are safe and appropriately tested. What plaintiff has not pointed to, however, is Dr. Blume or Dr. Parisian's identification of any internal company standard that required defendants to test their HRT products after market release.

*2 Plaintiff also contends that she has uncovered new evidence in the form of three FDA guidances issued in 1995, 2001, and 2005 that "clearly establish how FDA expects manufacturers to react to safety signals." *Response* at 12. Plaintiff alleges that she stopped taking Premarin and [Provera](#) in 1998, so guidances released in 2001 and 2005 are inapplicable to the facts of this case. Even if they were issued while plaintiff was still taking HRT drugs, neither guidance demands that manufacturers must conduct further testing. The 2001 FDA guidance outlines the kind of adverse events that drug manufacturers must report to the FDA, but it does not require further testing of drugs already on the market. *Id.*, ex. 55. The 2005 guidance provides suggestions for good practices, including investigation of safety signals through studies. Every page of the guidance, however, is marked "Contains Nonbinding Recommendations." *Id.*, ex. 56. It is unclear whether either Dr. Parisian or Dr. Blume relied on the 1995 guidance. In any case, the guidance is similarly unhelpful. It details recommendations for conducting studies when developing combination HRT drugs. It does not, however, require manufacturers to perform additional tests on drugs already on the market. *Id.*, ex. 54. Accordingly, Dr. Parisian and Dr. Blume cannot reliably base their opinions that defendants should have conducted additional tests on Premarin and [Provera](#) on either the 1995, 2001, or 2005 FDA guidances.

Plaintiff's next argument, that FDA regulations "establish a duty to study, if not an absolute statutory requirement for study," *response* at 12, is unpersuasive. To support this point, plaintiff points to Dr. Parisian's observation that FDA regulations require drug companies to alter label warnings once an association between a drug and [cancer](#) is revealed, and that a company must study its products before applying for a labeling change. These concepts do not, without a further link, establish a basis for Dr. Parisian's opinion that defendants were required to perform further testing in this case. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 519, 139 L.Ed.2d 508 (1997) (*Daubert* does not require courts to admit opinion testimony if there is "too great an analytical gap between the data and the opinion proffered"). Finally, plaintiffs contend that the PhRMA Code of Pharmaceutical Marketing Practices constitutes a written industry standard. Although this code addresses ethical interactions

between pharmaceutical manufacturers and healthcare professionals, it does not establish industry standards for post-market drug testing.²

An expert witness cannot opine that defendants breached a standard of care unless that standard exists. Because plaintiff cannot point to any objective standard relied on by Dr. Parisian or Dr. Blume that required defendants to perform additional testing, plaintiff has not shown that the failure to test opinions are anything more than “subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 590, 113 S.Ct. at 2795. Consequently, they are unreliable and inadmissible. We join several courts—including the MDL court—that have excluded Dr. Parisian and Dr. Blume's failure to test opinions in HRT litigation. *See, e.g., Hines v. Wyeth*, 2:04–0690, 2011 WL 2680842, at *6 (S.D.W.Va. July 8, 2011) (excluding Dr. Parisian's failure to test opinion); *Rivera Adams v. Wyeth*, 03–1713(JAF), 2010 WL 5072061, at *3 (D.P. R. Dec. 3, 2010) (excluding Drs. Parisian and Austin's failure to test opinions); *In re Prempro Prods. Liab. Litig.*, 4:03CV01507–WRW, 4:05CV00718–WRW, 2010 WL 5663003, at *3 (E.D.Ark. Sept.16, 2010) (excluding Drs. Parisian, Blume, and Austin's failure to test opinions).

IV

*3 Defendants argue that we should exclude Dr. Parisian and Dr. Blume's testimony entirely. They complain that, based on experiences in other HRT trials, “their testimony amounts to little more than reading portions of documents and offering personal commentary untethered to any objective standard.” *Mot.* at 8. Plaintiff responds that these experts will offer testimony in other areas, including FDA regulation, types of available studies, drug labeling standards and whether defendants' drug labels were accurate, and the scope of the FDA's authority. Defendants acknowledge that this type of testimony “ordinarily would not be objectionable, if that were in fact what these witnesses did.” *Reply* at 9.

We are unwilling to exclude helpful expert testimony in its entirety based on conjecture about what might happen at trial. The FDA drug approval process, FDA regulations, and protocols of drug labeling are topics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case. To be clear, this court will not permit either Dr. Parisian or Dr. Blume to merely recite or summarize documents. *See In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y.2009) (limiting Dr. Parisian's commentary on documents and exhibits to “explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.”). They must provide some analysis, opinion, or expertise when testifying about the FDA regulatory process and drug labeling. Objections to narrative testimony, however, are best made at trial.

Finally, defendants object to portions of Dr. Parisian and Dr. Blume's expert reports that offer opinions on defendants' corporate intent, motive, and knowledge. Both expert reports frequently and improperly opine about Wyeth's intent. *See, e.g., Mot.*, ex. 20 at 28 (“[t]he intent of Wyeth's paper was ...”); *id.*, ex. 21 at 23 (“[i]nternal Wyeth documents demonstrate that the company did not intend ...”). Dr. Parisian and Dr. Blume may not offer opinions concerning defendants' motive, intent, knowledge, or other state of mind.

V

IT IS ORDERED GRANTING IN PART defendants' motion to exclude opinions of plaintiff's experts Drs. Parisian, Blume, and Austin (doc. 79). Defendants' motion to exclude Dr. Austin's testimony is **DENIED** on grounds of mootness. Defendants' motion to exclude Dr. Parisian and Dr. Blume's failure to test opinions is **GRANTED**. Defendants' motion to exclude all of Dr. Parisian and Dr. Blume's testimony is **DENIED**. Our ruling is without prejudice to defendants making appropriate objections at trial.

All Citations

Not Reported in F.Supp.2d, 2012 WL 1204081

Footnotes

- 1 This action was formerly part of a multidistrict litigation (“MDL”) in the Eastern District of Arkansas. Plaintiff initiated an individual action here pursuant to the MDL judge's order.
- 2 For example, the code discusses appropriate items that manufacturers can give to healthcare professionals. *Reply*, ex. 4.

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KeyCite Yellow Flag - Negative Treatment

Distinguished by [Doe v. Independent School District 31](#), D.Minn., August 14, 2020

2016 WL 4039271

Only the Westlaw citation is currently available.

United States District Court, E.D. Pennsylvania.

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES
PRACTICES, AND PRODUCTS LIABILITY LITIGATION.

This Document Relates to:

Rana Terry, as Personal Representative and Administrator of the Estate of Denice Hayes, Deceased, Plaintiff,

v.

McNeil-PPC, Inc., McNeil Consumer Healthcare, and Johnson & Johnson, Inc., Defendants.

MDL NO. 2436

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2:13-md-02436

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Civil Action No. 2:12-cv-07263

|

Signed 07/28/2016

MEMORANDUM

[Stengel](#), District Judge

*1 This case is part of a Multidistrict Litigation (MDL) involving claims of liver damage from the use of [Tylenol](#) at or just above the recommended dosage.¹ This is the first “bellwether” case scheduled for trial.² The plaintiff plans to offer Dr. Cheryl Blume as a pharmacovigilance and regulatory expert. The defendants move to exclude parts of her testimony under [Daubert](#). For the reasons stated below, I will grant their motion in part and deny it in part.³

I. LEGAL STANDARD

The admissibility of expert testimony is governed by [Federal Rules of Evidence](#) 702 and 703 as well as by [Daubert v. Merrell Dow Pharms., Inc.](#), 509 U.S. 579 (1993), and its progeny.⁴ See [In re Paoli RR Yard PCB Litigation \(Paoli II\)](#), 35 F.3d 717, 735 (3d Cir. 1994). “Under the Federal Rules of Evidence, a trial judge acts as a ‘gatekeeper’ to ensure that ‘any and all expert testimony or evidence is not only relevant, but also reliable.’ ” [Pineda v. Ford Motor Co.](#), 520 F.3d 237, 243 (3d Cir. 2008)(quoting [Kannankeril v. Terminix Int’l, Inc.](#), 128 F.3d 802, 806 (3d Cir. 1997)). The Third Circuit recognizes a “liberal policy of admissibility” regarding [Rule 702](#). [Pineda](#), 520 F.3d at 243 (quoting [Kannankeril](#), 128 F.3d at 806); [United States v. Schiff](#), 602 F.3d 152, 173 (3d Cir. 2010).⁵

“[B]ecause expert evidence is often more misleading than other evidence, Rule 403 gives a judge more power over experts than over lay witnesses.” [In re Paoli RR Yard PCB Litigation \(Paoli II\)](#), 35 F.3d 717, 747 (3d Cir. 1994). However, “in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue— something other than the general complexity of scientific evidence.” [Id.](#)

a. Rule 702

*2 Federal Rule of Evidence 702 has three major requirements: 1) the expert must be qualified; 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and 3) the testimony must assist the trier of fact.⁶ Pineda, 520 F.3d at 243 (citing Kannankeril, 128 F.3d at 806). 702's inquiry should be a "flexible one." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993).

i. Expert Must Be Qualified

An expert's qualifications may include education, provided it is in a field related to the one in which the expert intends to testify. Fedor v. Freightliner, Inc., 193 F. Supp. 2d 820, 827 (E.D. Pa. 2002). Overall, the court will consider both academic training and practical experience to determine if the expert has "more knowledge than the average lay person" on the subject. Id. at 827-28 (citing Waldorf v. Shuta, 142 F.3d 601, 627 (3d Cir. 1998)). "An expert may be generally qualified but may lack qualifications to testify outside his area of expertise." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 322 (3d Cir. 2003).

However, this does not mean that the "best qualified" expert must testify. "[W]itnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified." Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1995).⁷ "Rule 702 and Daubert put their faith in an adversary system designed to expose flawed expertise." U.S. v. Mitchell, 365 F.3d 215, 244-45 (3d Cir. 2004)(citations omitted). "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Id. at 244 (citations omitted).

ii. Expert's Methods Must be Reliable

This Circuit interprets the second factor as one of "reliability," i.e., the testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable. Pineda, 520 F.3d at 244. An expert's opinion need not be correct, only reliable. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 744 (3d Cir. 1994)("This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." (emphasis in original)). "[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." Daubert, 509 U.S. at 592. "[I]t is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence." In re TMI Litig., 193 F.3d 613, 705 (3d Cir. 1999)(citing Paoli II, 35 F.3d at 744).⁸

*3 "Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 158 (1999). Judges considering this factor should look to whether a theory, technique, or opinion can be tested or has been subject to peer review or publication. Daubert, 509 U.S. at 593. "The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." Id. at 594. A court should also consider the known or potential rate of error involved in a scientific method. Id. "Reliability" does not require that a technique or methodology be generally accepted by a scientific community. Id. See also id. at 597-98. However, "[w]idespread acceptance can be an important factor in ruling particular evidence admissible" while a minimally supported technique "may properly be viewed with skepticism." Id.

iii. Expert Must be Helpful

The third factor “is typically understood in terms of whether there is a sufficient ‘fit’ between the expert's testimony and the facts that the jury is being asked to consider.” United States v. Schiff, 602 F.3d 152, 172-73 (3d Cir. 2010)(citing Daubert, 509 U.S. at 591). See also In re: TMI Litigation, 193 F.3d 613, 670 (3d Cir. 1999). This factor is about relevance. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” Daubert, 509 U.S. at 591 (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18). “Rule 702's ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” Id. at 591-92.

b. Rule 703

Under Federal Rule of Evidence 703, the data underlying the expert's opinion is the central focus. Rule 703 states:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

FED. R. EVID. 703. The trial court must evaluate whether the data used by an expert is reasonably relied upon by experts in the field. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747-49 (3d Cir. 1994).

II. Dr. Blume's Proffered Opinions

The plaintiff plans to offer Dr. Blume as an expert in pharmacovigilance and risk reduction, including drug labeling. “Pharmacovigilance principally involves the identification and evaluation of safety signals.” FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, at 4 (2005)(Pl. Ex. 7, filed under seal).⁹ The term “safety signal” “refers to a concern about an excess of adverse events compared to what would be expected to be associated with a product's use.” Id. Safety signals can be found in a variety of sources, including post-marketing data, preclinical data, or case reports offering adverse effects of the drug. See id.¹⁰ A single well-documented adverse event report (AER) may be a safety signal, depending on the circumstances of the adverse event (i.e., the only explanation for the event would be the drug itself). See id. at 4-5.¹¹ Signals do not establish causation, per se; instead, they simply indicate that further investigation into the drug's effects is needed. See id. at 4, 12-16. Investigation of a signal may include both randomized trials and “carefully designed nonrandomized observational studies of the product's use in the ‘real world,’ ” such as registries and surveys. Id. at 12-17.

*4 “After a signal is identified, it should be further assessed to determine whether it represents a potential safety risk and whether other action should be taken.” Id. See also id. at 17-18. If the investigation finds that the signal poses a risk to consumer safety, the drug label's warnings may need to be altered or the company may need to withdraw the drug from the market. See K. Kwong Dep., Jan. 25, 2014 at 163, 219-20 (Pl. Ex. 6, filed under seal).¹² A drug company does not have to establish that the drug actually caused the adverse effects being investigated before taking a risk reduction action.¹³

Dr. Blume plans to offer an opinion that McNeil should have identified safety signals showing that hepatotoxicity was possible at or near 4 grams of acetaminophen— the active ingredient in Tylenol—as early as the early 2000s and that the defendants

failed to take appropriate risk mitigation steps.¹⁴ In her opinion, the labeling on Extra Strength Tylenol did not fully inform consumers of hepatotoxicity risk. In short, Dr. Blume's opinion offers a standard for an appropriate label for Extra Strength Tylenol, under all the known and available circumstances.

*5 To reach her conclusions, Dr. Blume independently reviewed several sources of information: toxicology studies, clinical trial data, case reports, case series, and the results of adverse event databases, along with depositions and related internal documents.¹⁵ She also reviewed third-party assessments of the risk, including independent audits of the defendants' pharmacovigilance practices.¹⁶

III. Dr. Blume is a Qualified Pharmacovigilance Expert

Dr. Cheryl Blume is the President of Pharmaceutical Development Group, Inc. (PDG), a multi-disciplinary pharmaceutical services firm that specializes in the development, registration, and monitoring of drugs and drug company activity for pharmaceutical companies.¹⁷ She received a Ph.D. in Pharmacology and Toxicology from The West Virginia University Medical Center. Dr. Blume's graduate study and research was funded by a National Institutes of Health (NIH) fellowship.

After completing her graduate fellowship, Dr. Blume joined Mylan Laboratories, one of the world's largest pharmaceutical companies. During her 18-year career with Mylan, Dr. Blume served in several senior scientific, management, and regulatory positions, including Corporate Vice President, Technical Director, Director of Pharmacology, and Assistant Director of Regulatory Affairs. Additionally, she spent five years as an Executive Vice President, Chief Operations Officer, and Board Member of Somerset Pharmaceuticals, Inc. She started PDG in 1999. During her career, she has worked with generic drugs, brand-name drugs, and drugs regulated by both the New Drug Application (NDA) system and the monograph system.

Over the course of her professional career, Dr. Blume has written, consulted on, or been responsible for the labeling and/or promotional materials for more than 100 different pharmaceutical products. She is also an Affiliate Associate Professor to the Voluntary Faculty of the Department of Molecular Pharmacology and Physiology at the University of South Florida's College of Medicine in Tampa, Florida.

Dr. Blume has been qualified as a pharmacovigilance expert in numerous drug products liability actions.¹⁸ From all that has been provided, she is well-qualified to serve as a pharmacovigilance and regulatory expert in this case.

IV. The Defendants' Daubert Challenge to Dr. Blume's Testimony

*6 The defendants move to exclude Dr. Blume's opinions on:

- 1) The cause or mechanism of acetaminophen-induced hepatotoxicity;
- 2) Risk factors for acetaminophen-induced hepatotoxicity;
- 3) Case reports or adverse events reports (AERs);
- 4) Alleged deficiencies in McNeil's pharmacovigilance process;
- 5) Actions that have been considered by the FDA;
- 6) Johnson & Johnson's Credo; and
- 7) Marketing materials of the defendants.

They claim that she cannot testify because she is not qualified or prepared to offer an opinion about causation in this case. They also claim that her methodology does not pass muster under Daubert or the Federal Rules of Evidence.

a. Testimony on Medical Causation and Risk Factors

First, the defendants argue that the “Acetaminophen-related [Hepatotoxicity](#) events” section of Dr. Blume's report (p. 22-36) includes information she cannot offer as an expert because she is not a medical doctor.

The plaintiff counters that Dr. Blume is a regulatory expert, offering an opinion about general causation from a pharmacovigilance perspective (i.e., whether the available information signals a risk that liver damage can occur at or near 4 grams of [acetaminophen](#)). She intends to discuss the processes required of companies carrying out pharmacovigilance. Pharmacovigilance is essentially the methods pharmaceutical companies use to assess risk to consumers.¹⁹ The plaintiff argues that, as a pharmacovigilance expert, Dr. Blume does not necessarily need to be a medical doctor. I agree.²⁰

*7 Dr. Blume is qualified as a pharmacovigilance expert and developed her opinion as such an expert would. She approached her analysis by conducting research in the way the FDA would: reviewing the available information about the risk of liver damage at or close to the recommended dose of 4 grams to see if this information raises “safety signals” requiring the defendants to act.²¹ Her testimony about the risk of liver damage at recommended doses will be permitted.²²

The defendants also argue Dr. Blume cannot testify about risk factors for acetaminophen-induced liver damage—such as alcohol use, preexisting liver diseases, etc.—because they do not “fit” this case. They claim this information is outside the scope of Dr. Blume's area of expertise.

Dr. Blume offers an opinion about when certain “vulnerable populations” may be at risk to develop liver damage at recommended doses from a pharmacovigilance perspective. As she explains in her deposition, she reviewed available information about whether, when, and how [acetaminophen](#) posed a risk of liver damage. This discussion provides background for her analysis of whether the defendants acted appropriately in light of this information. Her discussion of risk factors, as they pertain to the defendants' pharmacovigilance duties, passes muster under Daubert.

b. Reliance on AERs or Case Reports²³

The defendants argue that Dr. Blume's opinion should not be based on case reports or adverse event reports (AERs) because they are unreliable.²⁴ Using AERs to evaluate the risk of safety concerns to consumers is a methodology often used in pharmacovigilance by the FDA and others in the field.²⁵ FDA advisory committees and working groups have relied on AERs to evaluate risks to consumers regarding [acetaminophen](#) toxicity at the recommended dose.²⁶ AERs are especially important to the field of pharmacovigilance in evaluating risk.²⁷ A single well-documented adverse event report (AER) may be a safety signal, depending on the circumstances of the adverse event (i.e., the only explanation for the event would be the drug itself).²⁸ Given that AERs are sources of information commonly relied upon by pharmacovigilance experts, Dr. Blume's use of AERs in formulating her opinions would be appropriate in this case.²⁹ See FED. R. EVID. 703 (“An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.”).³⁰

c. Pharmacovigilance Deficiencies³¹

*8 The defendants claim that Dr. Blume should not be permitted to testify about McNeil's pharmacovigilance deficiencies. First, they claim this testimony does not “fit” the case. I disagree. Whether the defendants took the proper steps to recognize potential problems or “safety signals” related to Extra Strength [Tylenol](#) is entirely relevant to notice, knowledge, and defendants'

state of mind. The defendants are required to monitor potential safety concerns with their products (i.e., pharmacovigilance). If they were not doing so, a jury could find they placed an unreasonably dangerous product on the market.

The defendants also argue that their prior “bad acts” before 2010 are not admissible and would be confusing to the jury. They claim only those deficiencies in adverse event reporting around the time of the decedent's death are the only deficiencies that are relevant. I again disagree. A pattern of deficiencies in pharmacovigilance could be relevant to the plaintiff's failure-to-warn and punitive damages claims. The deficiencies in the defendants' adverse event reporting in the years prior to the decedent's death are highly probative evidence of notice, intent, and knowledge of the defendants.³² This information is relevant to Dr. Blume's pharmacovigilance opinion about the adequacy of the defendants' risk reduction measures prior to the decedent's death.

d. Testimony about Corporate State of Mind

The defendants argue that Dr. Blume's testimony that the defendants “behaved negligently in conducting its business” would be an improper legal opinion. See [Berkeley Inv. Grp., Ltd. v. Colkitt](#), 455 F.3d 195, 217 (3d Cir. 2006). See also [Wolfe v. McNeil-PPC, Inc.](#), No. CIV.A. 07-348, 2011 WL 1673805, at *8 (E.D. Pa. May 4, 2011) (citing [Berkeley](#), 455 F.3d at 217); [Wolfe v. McNeil-PPC, Inc.](#), 881 F. Supp. 2d 650, 662 (E.D. Pa. 2012). The defendants claim that the jury, not the plaintiff's expert, is to decide whether the defendants acted negligently.

An expert cannot usurp the role of the judge or jury. See, e.g., [Berkeley Inv. Grp., Ltd. v. Colkitt](#), 455 F.3d 195, 217 (3d Cir. 2006). “Notwithstanding this admonition, the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties.” [Id.](#) at 218. I agree that Dr. Blume cannot opine that the defendants breached their legal duties, offer an opinion about what the defendants' intent was, or offer testimony about internal documents which the jury themselves can easily interpret on their own.³³

*9 Dr. Blume can, however, offer testimony on what certain technical regulatory documents mean and how they exemplify compliance with industry standards/customs.³⁴ “The FDA drug approval process, FDA regulations, and protocols of drug labeling are topics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case.” [Johnson v. Wyeth LLC](#), No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012). This testimony will aid the jury in determining whether the defendants fell below the industry standard for labelling, warning, or dose levels and to what extent the defendants knew or should have known about the risk of liver damage.

e. Actions Considered by the FDA but Not Yet Taken

The defendants argue that Dr. Blume's testimony about actions that FDA has considered but not yet taken is irrelevant, misleading, a waste of judicial resources, and/or unfairly prejudicial. Specifically, the defendants take issue with FDA Working Group recommendations or proposals that were not adopted by the FDA. If a pharmaceutical company would typically take those FDA recommendations or working group proposals into consideration in determining how to act in terms of pharmacovigilance goals, this information would be relevant. Whether it is unfairly prejudicial under Rule 403—the argument the defendants really appear to be making, which is addressed in a separate motion in limine—would be a determination I would need to make in context. I will defer a ruling based on Rule 403 until trial.

f. Testimony about Johnson & Johnson's Credo

*10 The defendants argue that Dr. Blume should not be permitted to opine about Johnson & Johnson's Credo or mission statement. They claim that their own internal standard of care should not be presented as a legal standard of care; such information could mislead a jury. I agree. The defendants' own Credo should not be held out as the legal standard by which it should conduct its affairs. See [Johnson v. Mountainside Hospital](#), 239 N.J. Super. 312, 323 (App. Div. 1990) (“It was potentially

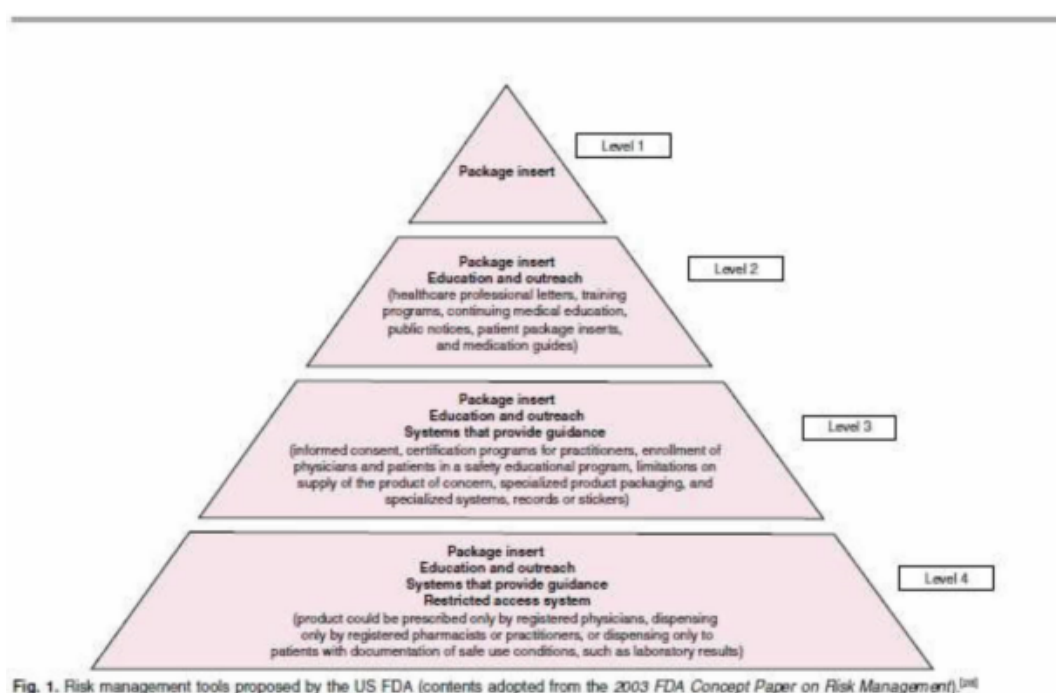
misleading because it attempted to exalt an exhortatory statement in the by-laws of the Hospital into the legal standard for determining whether or not the defendant physicians committed malpractice. The relevant legal standard is defined by law.”). Additionally, any probative value the Credo may serve would be substantially outweighed by potential prejudice of the jury confusing this standard what was legally required.³⁵ See *In re Paoli RR Yard PCB Litigation (Paoli II)*, 35 F.3d 717, 747 (3d Cir. 1994)(explaining how “Rule 403 gives a judge more power over experts than over lay witnesses” but this exclusion of evidence should only happen when they is “something particularly confusing about the scientific evidence at issue—something other than the general complexity of scientific evidence”).

Testimony by Dr. Blume about Johnson & Johnson's Credo will be excluded.

g. Testimony about Marketing Materials

Lastly, the defendants argue that Dr. Blume's opinions concerning marketing materials are irrelevant and/or not helpful to the jury because it is unclear what advertisements the decedent saw. The plaintiff counters that Dr. Blume is qualified to offer a marketing opinion and the information is relevant to what the decedent and her sister were led to believe about the drug.

Pharmacovigilance involves several levels of risk reduction, as shown by this diagram from an article co-authored by Dr. Kwong, McNeil's Director of Pharmacovigilance.³⁶



Several of those levels involve communicating with consumers about known risks. For an over-the-counter product, like Tylenol, marketing and advertising is an important way of communicating with consumers. For this reason, marketing would be relevant to pharmacovigilance and Dr. Blume's testimony. Dr. Blume may offer an opinion about marketing materials as they relate to pharmacovigilance.

V. CONCLUSION

For the foregoing reasons, I will **GRANT** the defendants' motion in part and **DENY** it in part. Dr. Blume's testimony about the Johnson & Johnson Credo will be excluded, as explained above. All other testimony will be permitted, in accordance with the above.³⁷

*11 An appropriate Order follows.

All Citations

Not Reported in Fed. Supp., 2016 WL 4039271

Footnotes

- 1 See Master Compl., 13-md-2436, Doc. No. 32. There are over two hundred other cases included in this MDL, along with several similar cases in New Jersey state court.
- 2 A “bellwether” case is a test case. “Bellwether” trials should produce representative verdicts and settlements. The parties can use these verdicts and settlements to gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible. See FEDERAL JUDICIAL CENTER, MANUAL FOR COMPLEX LITIGATION, FOURTH EDITION 360 (2004); DUKE LAW CENTER FOR JUDICIAL STUDIES, MDL STANDARDS AND BEST PRACTICES 16-21 (2014).
- 3 In making my decision, I have reviewed all of the materials submitted as attachments to the parties' briefs, including those submitted during oral argument.
- 4 Daubert held that the Federal Rules of Evidence, specifically [Rule 702](#), controlled the issue of when experts were qualified. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 587-88 (1993). It found that [Rule 702](#) superseded the Court's prior precedent on the subject found in Frye v. United States, 54 App.D.C. 46, 47, 293 F. 1013, 1014 (1923). Id. at 587. Daubert went on to clarify what was required under [Rule 702](#), as compared to Frye. See id. at 589-598.
- 5 See also Holbrook v. Lykes Brothers Steamship Company, Inc., 80 F.3d 777, 780 (3d Cir. 1996); Zaprala v. USI Servs. Gp., Inc., No. 09-1238, 2013 WL 1148335, at *6 (E.D. Pa. Mar. 20, 2013)(quoting Pineda, 520 F.3d at 243).
- 6 [Federal Rule of Evidence 702](#) states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

 - (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
 - (b) the testimony is based on sufficient facts or data;
 - (c) the testimony is the product of reliable principles and methods; and
 - (d) the expert has reliably applied the principles and methods to the facts of the case.

[FED. R. EVID. 702](#).
- 7 See also Keller v. Feasterville Family Health Care, 557 F. Supp. 2d 671, 675 (E.D. Pa. 2008)(Rice, J.).
- 8 See also [FED. R. EVID. 702](#), Advisory Committee Note (2000 Amendments)(“Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.”) (citing Bourjaily v. United States, 483 U.S. 171 (1987)).

- 9 See also Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance).
- 10 See also E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal)(McNeil's Vice President for Scientific Affairs explaining that information, including AERs, may lead to a label change as part of pharmacovigilance).
- 11 See also K. Kwong Dep., Jan. 25, 2014 at 166 (Pl. Ex. 6, filed under seal).
- 12 See also Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance); E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal)(McNeil's Vice President for Scientific Affairs explaining that information, including AERs, may lead to a label change as part of pharmacovigilance).

Kenneth Kwong, McNeil's Director of Pharmacovigilance, identified four distinct levels of risk mitigation increasing in intensity: Level 1 (labeling), Level 2 (labeling, education and outreach), Level 3 (labeling, education and outreach, and systems that provide guidance), and Level 4 (labeling, education and outreach, systems that provide guidance, and restricted access). See K. Kwong Dep., Jan. 25, 2014 at 219-20 (Pl. Ex. 6, filed under seal); Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kwong).

In the 1990s, McNeil voluntarily relabeled Tylenol to include alcohol warnings after finding that the literature and other sources indicated a risk of liver damage. See E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal).

- 13 See In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 5173568 at *7 (N.D. Ohio Jun. 18, 2010)(“The question of whether these AERs constituted a safety signal requires someone with expertise in pharmacovigilance. The expert must determine whether, given all the information available to GEHC at the time, the AERs gave rise to a safety signal alerting GEHC to the risks associated with administering Omniscan, particularly to the renally impaired. Hence, whether the four AERs supported a clinical diagnosis of NSF is irrelevant to the question of whether the AERs constituted a safety signal.”).

This is especially true in this case, since Extra Strength Tylenol was governed by a Tentative Final Monograph, not a Final Monograph. See Letter from FDA re: FOIA request, Nov. 17, 2011 (Pl. Ex. 17, filed under seal); L. Pawelski Dep., Fe. 28, 2014 at 112-17 (Pl. Ex. 20, filed under seal). See also Memorandum Denying Motion for Summary Judgment on Failure-to-Warn Claim at 10-15 (Doc. No. 181); Memorandum Denying Motion for Summary Judgment on Design Defect Claim at 12-18 (Doc. No. 183).

- 14 See C. Blume Expert Report, May 5, 2014 at ¶¶ 100, 120 (Doc. No. 124, Ex. A).
- 15 See C. Blume Expert Report, May 5, 2014 at ¶ 17, Sec. 3 (Doc. No. 124, Ex. A).

Among these references, Dr. Blume cites Larson, A.M., et al., Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study, Hepatology, 2005 Dec.: 42(6): 1364-1372 (Doc. No. 154, Ex. 22). The defendants filed a separate motion to exclude the use of this article. See Motion to Exclude Opinion Testimony of Cheryl Blume based on Supplemental Data, Jan. 29, 2016 (Doc. No. 193). I denied that motion. See Memorandum and Order Denying Defendants' Motion to Exclude Plaintiff's Expert Testimony Based on Larson Article/ALFSG Data, Jul. 14, 2016 (Doc. No. 224, 225). I see nothing improper with how Dr. Blume has used the Larson article (which she only cites once in her report)—along with other evidence—in rendering her opinion.

- 16 See C. Blume Expert Report, May 5, 2014 at ¶ 13 (Doc. No. 124, Ex. A).
- 17 See <http://www.pharmdevgroup.com/about-pdg/>.

The information about Dr. Blume's qualifications can be found in her expert report (Doc. No. 124, Ex. A), in her Curriculum Vitae (Doc. No. 124, Ex. A at Ex. 1), and her deposition (Doc. No. 124, Ex. B). The defendants do not challenge Dr. Plunkett's qualifications, per se; however, an overview of her credentials is helpful in explaining my rulings.

18 See, e.g., [In Re: Gadolinium-Based Contrast Products Liab. Litig.](#), No. 1:08 GD 50000, 2010 WL 1796334, at *15-17 (N.D. Ohio May 4, 2010); [Wright v. American Home Products Corp.](#), 557 F. Supp. 2d 1032, 1037-38 (W.D. Mo. 2008)(“Blume is clearly qualified to testify about the risks and benefits of [Pondimin](#) as it relates to general industry practice and she is qualified as to any general industry standards Wyeth followed or failed to follow prior to marketing and distributing [Pondimin](#).”); [Fraser v. Wyeth](#), No. 3:04cv1373, 2014 WL 129172, at *5 (D. Conn. Jan. 14, 2014)(“Dr. Blume, based on her extensive experience, testified as to the industry standard of pharmacovigilance... and opined that Wyeth had violated that standard with respect to the [Prempro](#) label.”); [In Re Yasmin & Yaz Mktg., Sales Practices & Prod. Liab. Litig.](#), No. 3:09-md-02100, MDL No. 2100, 2011 WL 6302287, at *23 (S.D. Ill. Dec. 16, 2011)(qualifying Blume as a pharmacovigilance an regulatory expert); [In re: Neurontin Mktg Sales Practice & Prod Liab. Litig.](#), 612 F. Supp. 2d 116, 158 (D. Mass. 2009)(“Dr. Blume is amply qualified at least to evaluate the adverse event data and other sources of information regularly used by the FDA and industry professionals.”). See also [Decker v. GE Healthcare Inc.](#), 770 F.3d 378, 393 (6th Cir. 2014)(discussing Dr. Blume's qualifications as pharmacovigilance expert).

19 See [In Re: Gadolinium-Based Contrast Products Liab. Litig.](#), No. 1:08 GD 50000, 2010 WL 1796334, at *15 (N.D. Ohio May 4, 2010)(discussing FDA's Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (Mar. 2005)).

20 See [Decker v. GE Healthcare Inc.](#), 770 F.3d 378, 394 (6th Cir. 2014)(“The district court concluded that because Blume was a pharmacovigilance expert, irrespective of whether she was a medical doctor, she was qualified to reliably testify as to the significance of the AERs. Conversely, the district court concluded that because Gaspari was not a pharmacovigilance expert, even though he was a medical doctor, he was not qualified to testify reliably regarding the significance of the AERs. The district court did not abuse its discretion in reaching either conclusion.”).

Even McNeil's own Director of Pharmacovigilance Kenneth Kwong, M.D., Ph.D. noted the distinction between what a pharmacovigilance professional does and medical professional does. See [K. Kwong Dep.](#), Jan. 25, 2014, at 62 (“Even hepatologists might not be necessarily the best person to look at it because someone who practice medicine is quite different from someone who look at pharmacovigilance”) and at 58 (“Both of them have years of drug safety experience. They might not necessarily be hepatologists. In drug safety we deal with different drug safety issue, there's not one particular type of area. With their years experience [sic] they're well qualified to be physician to deal with liver toxicity.”) (Pl. Ex. 6, filed under seal).

21 See [In Re: Gadolinium-Based Contrast Products Liab. Litig.](#), No. 1:08 GD 50000, 2010 WL 1796334, at *15 (N.D. Ohio May 4, 2010)(“[T]he Court finds that Dr. Blume's background in pharmacology, toxicology and risk assessment qualify her to opine on NSF causation, the stability of [Omniscan](#), and the free gadolinium theory. Dr. Blume is also qualified to interpret the results of any of GEHC's toxicology, pharmacology or [pharmacokinetic studies](#) and to opine on the significance of the results. The Court finds that Dr. Blume may testify, based on the facts adduced at trial (including GEHC internal studies and documents), on the accuracy and adequacy of the toxicology, pharmacology and pharmacokinetics data appearing on the [Omniscan](#) label at the time a given plaintiff was administered [Omniscan](#).”); [In re: Neurontin Mktg Sales Practice & Prod Liab. Litig.](#), 12 F. Supp. 2d 116, 158 (D. Mass. 2009)(“In performing this review, Dr. Blume states that she used the same methods that she employs when preparing a drug development for submission to the FDA.”)(qualifying Blume as a regulatory expert who can provide an opinion on general causation).

22 See, e.g., [Daniel v. Wyeth, Inc.](#), 15 A.3d 909, 926 (Pa. Super. 2011)(explaining and Dr. Blume was qualified as an expert on causation even though she was not a medical doctor); [Decker v. GE Healthcare Inc.](#), 770 F.3d 378, 393-95 (6th Cir. 2014)(same).

- 23 Dr. Blume does not rely solely on AERs in rendering her opinions. She considers many other sources typically used by pharmacovigilance experts (i.e., FDA documents, internal documents, etc.), in rendering her opinions. Her sources all appear to be appropriate under [Rule 702](#) and [703](#). Any weaknesses in her sources can be explored during cross-examination.
- 24 In a related motion in limine, I ruled that AERs were admissible, in the least, to show “notice.” I also found that it may be appropriate for experts to rely on AERs so long as they did so in a reliable manner. [See Memorandum on Defendants' Motions in Limine \(MIL 1\)](#), Apr. 19, 2016 at 3-11 (Doc. No. 336)(denying defendants' motion to exclude AERs).
- 25 [See FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment](#), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (“The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.... FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to reporting regulations and responding to outside requests for information. The reports in FAERS are evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to monitor the safety of products after they are approved by FDA. If a potential safety concern is identified in FAERS, further evaluation is performed.”); [Decker v. GE Healthcare Inc.](#), 770 F.3d 378, 394 (6th Cir. 2014)(“The district court concluded that because Blume was a pharmacovigilance expert, irrespective of whether she was a medical doctor, she was qualified to reliably testify as to the significance of the AERs. Conversely, the district court concluded that because Gaspari was not a pharmacovigilance expert, even though he was a medical doctor, he was not qualified to testify reliably regarding the significance of the AERs. The district court did not abuse its discretion in reaching either conclusion.”).
- 26 [See, e.g., FDA Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity](#), Feb. 26, 2008, at 11 (Pl. Ex. 8, filed under seal).
- 27 The defendants question Dr. Blume's reliance on specific AERs and whether they are relevant to her opinions in this case. They argue that a number of these AERs are not substantially similar to the plaintiff's case. From what I see, the AERs relied on by Dr. Blume have some relation to this case (i.e., they involve fasting, [acetaminophen](#) at recommended doses, etc.). Any dissimilarities in these cases, as compared to the plaintiff's medical history, are appropriately explored on cross-examination. If Dr. Blume discusses AERs that do not involve [acetaminophen](#) at or near recommended doses, fasting/malnutrition, [liver injury](#), or other conditions similar to the plaintiff's case, the defendants may raise an objection at trial. [See In re Viagra Prods. Liab. Litig.](#), 658 F. Supp. 2d 950, 964 (D. Minn. 2009)(excluding as irrelevant Dr. Blume's testimony regarding adverse event reports addressing [Viagra](#) and eye conditions other than non-arteritic anterior is chemic [optic neuropathy](#) (NAION), the eye condition at issue in the case).
- 28 [See FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment](#), at 4-5 (2005)(Pl. Ex. 7, filed under seal). [See also](#) Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, [Pharm. Dev. Regul.](#), 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal) (article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance); K. Kwong Dep., Jan. 25, 2014 at 166 (Pl. Ex. 6, filed under seal).
- 29 [See, e.g., In Re: Gadolinium-Based Contrast Products Liab. Litig.](#), No. 1:08 GD 50000, 2010 WL 1796334, at *11 (N.D. Ohio May 4, 2010)(explaining how AERs are often one of several sources relied on by experts like Blume); [In re: Neurontin Mtkg. Sales Practice & Prod. Liab. Litig.](#), 12 F. Supp. 2d 116, 153, 157 (D. Mass. 2009)(explaining how AERs may be used to support general causation theories by pharmacovigilance experts); [In re Phenylpropanolamine \(PPA\) Prods. Liab. Litig.](#), 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)(observing that “[n]on-epidemiological sources [such as AERs] are frequently utilized by experts in rendering scientific opinions[.]”).

- 30 Whether the AERs themselves are admissible at trial is a different question, which I will resolve when I see how they will be used at trial.
- 31 The defendants claim Dr. Blume's methodology regarding deficiencies in their adverse event reporting is not reliable because she does not review the AERs herself to determine if the defendants missed a safety signal during the relevant time frame. They also argue that her testimony about AERs should be excluded because she did not review the AERs herself, only a summary of them. Dr. Blume is considering whether the information found in the AERs raised a "safety signal" and whether the defendants appropriately addressed adverse events known to them. Dr. Blume's use of summaries of AERs and reports of AERs procedural deficiencies would be appropriate for the purpose of opining that the defendants' pharmacovigilance duties had been triggered by such information.
- 32 See also Memorandum on Defendants' Motions in Limine (MIL 7), Apr. 19, 2016 at 24-27 (Doc. No. 336)(denying defendants' MIL to exclude forms noting deficiencies in adverse event reporting).
- 33 See In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D. N.Y. 2004)("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony. As the Diet Drugs court stated in excluding testimony that the pharmaceutical defendant's conduct with respect to labeling was motivated by its desire to increase profits, '[t]he question of intent is a classic jury question and not one for the experts.' "); (quoting In re Diet Drugs, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. Jun. 20, 2000)); Heineman v. American Home Products Corp., No. 13-cv-02070-MSK-CBS, 2015 WL 1186777, at *12 (D. Colo. Mar. 12, 2015)(excluding Dr. Blume's opinions about defendants' state of mind); In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 950, 964-965 (D. Minn. 2009)("There is no indication in the record that the jury here would require special assistance to interpret the documents on which Dr. Blume bases her opinion that Pfizer was more worried about bad publicity than safety. Because the jury is equally capable of evaluating this particular evidence, Dr. Blume's opinion on this matter must be excluded."); Chandler v. Greenstone Ltd., No. C04-1300RSL, 2012 WL 882756, at *1 (W.D. Wash. Mar. 14, 2012)(excluding Dr. Blume's opinions on defendants' state of mind, intent, or knowledge); Johnson v. Wyeth LLC, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012)(excluding Dr. Blume's opinions on defendants' motive, intent, knowledge, or other state of mind); In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007)("The Court finds that Dr. Smith's opinion criticizing Bayer for inadequately evaluating the potential toxicity of Baycol, and asserting that Bayer ignored warnings is legal argument that does not qualify as expert testimony under Rule 702."); Tyree v. Boston Scientific Corp., 54 F. Supp. 3d 501, 564 (S.D. W. Va. 2014)("While internal corporate documents and executives' testimony are certainly relevant in this case, such evidence 'should be presented directly to the jury, not through an expert.' ") (quoting In re C.R. Bard, Inc., 948 F.Supp.2d 589, 628 (S.D. W.V. 2013)).
- 34 See Heineman v. American Home Products Corp., No. 13-cv-02070-MSK-CBS, 2015 WL 1186777, at *12 (D. Colo. Mar. 12, 2015)("[I]t may be necessary for Dr. Blume to explain the meaning or significance of certain words or concepts that might appear in such records—she may have to explain what a safety surveillance employee does, the hierarchy that oversees such employees, or the typical consequences of the event the record reflects—but the Plaintiffs have not shown that, armed with such records and Dr. Blume's explanations thereof, the trier of fact would be unable to reach a conclusion about the Defendants' knowledge of any labeling deficiencies without Dr. Blume's say-so."); In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D. N.Y. 2009)("Dr. Parisian's commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. She will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence."); Wright v. American Home Products Corp., 557 F. Supp. 2d 1032, 1038 (W.D. Mo. 2008)("Blume is clearly qualified to testify about the risks and benefits of Pondimin as it relates to general industry practice and she is qualified as to any general industry standards Wyeth followed or failed to follow prior to marketing and distributing Pondimin."); Fraser v. Wyeth, No. 3:04cv1373, 2014 WL 129172, *5 (D. Conn. Jan. 4, 2014)("Dr. Blume, based on her extensive experience, testified as to the industry standard of pharmacovigilance (see Trial Tr. Vol. II at 202-03), and opined that Wyeth had violated that standard with respect to the Prempro label (see, e.g., id. at 737-38 (testifying that the failure to include

information regarding the risk of dying from [breast cancer](#) in the [Prempro](#) label violated the duties of pharmacovigilance and the FDA regulations)).”).

- 35 The plaintiff argues that the defendants' Credo simply serves as an acknowledgement of the standard of care to which they must adhere. Johnson & Johnson's Credo requires more of its employees than the legal standard of care (i.e., putting consumers first and shareholders last). Allowing the company to be judged on this standard could discourage companies to create internal policies that go beyond what the law asks. See [Cast Art Indus., LLC v. KPMG LLP](#), 416 N.J. Super. 76, 106-07 (2010)(explaining how applying company's internal procedures with a higher standard of care than common-law standard could discourage companies from creating procedures that exceed common law duties), [rev'd on other grounds, Cast Art Indus., LLC v. KPMG LLP](#), 209 N.J. 208 (2012); [Branham v. Loews Orpheum Cinemas, Inc.](#), 819 N.Y.S.2d 250, 255 (App. Div. 2006)(“While a defendant's internal rules may be admissible as evidence of whether reasonable care was exercised, such rules must be excluded, as a matter of law, if they require a standard of care which transcends the traditional common-law standard of reasonable care under the circumstances.” (citations omitted)).
- 36 See Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, [Pharm. Dev. Regul.](#), 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance).
- 37 The defendants make several other cursory arguments about Dr. Blume's opinions. Those arguments not specifically addressed in this memorandum go to the weight of the evidence, not to its admissibility.

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2009 WL 10673979

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United States District Court, D. Arizona.

RESEARCH CORPORATION TECHNOLOGIES, INC., Plaintiff,

v.

MICROSOFT CORPORATION, Defendant.

CV-01-658-TUC-RCJ

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Signed August 18, 2009

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Filed 08/19/2009

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ORDER

ROBERT C. JONES, UNITED STATES DISTRICT JUDGE

I. INTRODUCTION

*1 Before the Court is Microsoft's Motion in Limine to Admit Comparison Images. The Court has considered arguments and pleadings on behalf of both parties. IT IS HEREBY ORDERED that Microsoft's Motion in Limine to Admit Comparison Images is GRANTED. (#958.)

II. BACKGROUND

Microsoft moves for the admission of four print outputs: (1) original print output that Microsoft's test team generated in 2002–2003, (2) original print comprised of duplicate DTX 1323 images generated by Gary Liao in April 2005, (3) original print output comprised of duplicate DTX 1323 images generated by Gary Liao in May 2009, and (4) original print output generated by RCT's expert, Dr. Jennifer Alford. These print outputs were generated using the accused Microsoft numbers, and it asserts that the technology has no impact on its customer's user experience, going toward a damage award. Microsoft asserts the images are relevant, not inadmissible hearsay, and authentic with declarations sufficient for admissibility. RCT counters that the images, as argued in its own Motion in Limine 3, are irrelevant, would amount to undue prejudice, inauthentic, and hearsay.

III. ANALYSIS

A. Standard for Motion in Limine

A motion *in limine* is a procedural device to obtain an early and preliminary ruling on the admissibility of evidence. Black's Law Dictionary defines it as “[a] pretrial request that certain inadmissible evidence not be referred to or offered at trial. Typically, a party makes this motion when it believes that mere mention of the evidence during trial would be highly prejudicial and could not be remedied by an instruction to disregard....” BLACK'S LAW DICTIONARY, 1038–39 (8th ed. 2004). Although the Federal Rules of Evidence do not explicitly authorize a motion *in limine*, the Supreme Court has held that trial judges are authorized to rule on motions *in limine* pursuant to their authority to manage trials. *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984)

A motion *in limine* is a request for the court's guidance concerning an evidentiary question. See *Wilson v. Williams*, 182 F.3d 562, 570 (7th Cir. 1999). Judges have broad discretion when ruling on motions *in limine*. See *Jenkins v. Chrysler Motors Corp.*, 316 F.3d 663, 664 (7th Cir. 2002). However, a motion *in limine* should not be used to resolve factual disputes or weigh evidence. See *C & E Services, Inc., v. Ashland Inc.*, 539 F. Supp. 2d 316, 323 (D.D.C. 2008). To exclude evidence on a motion in limine “the evidence must be inadmissible on all potential grounds.” *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004); *Kiswani v. Phoenix Sec. Agency, Inc.*, 247 F.R.D. 554 (N.D. Ill. 2008); *Wilkins v. K-Mart Corp.*, 487 F. Supp. 2d 1216, 1218-19 (D. Kan. 2007); *Allen v. City of N.Y.*, 466 F. Supp. 2d 545, 548 (S.D.N.Y. 2006). “Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Hawthorne Partners v. AT&T Tech, Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993). This is because although rulings on motions *in limine* may save “time, costs, effort and preparation, a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Wilkins*, 487 F. Supp. 2d at 1219.

*2 It is settled law that *in limine* rulings are provisional. Such “rulings are not binding on the trial judge [who] may always change his mind during the course of a trial.” *Ohler v. United States*, 529 U.S. 753, 758 n. 3 (2000); accord *Luce v. United States*, 469 U.S. 38, 41 (1984) (noting that *in limine* rulings are always subject to change, especially if the evidence unfolds in an unanticipated manner). “Denial of a motion in limine does not necessarily mean that all evidence contemplated by the motion will be admitted to trial. Denial merely means that without the context of trial, the court is unable to determine whether the evidence in question should be excluded.” *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d at 846.

B. Federal Rules of Evidence

Federal Rule of Evidence 402 provides: “All relevant evidence is admissible, except as otherwise provided....” Relevancy is defined as any “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401. Federal Rule of Evidence 403 provides: “Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” Fed. R. Evid. 403.

Expert witness testimony is admissible if it “will assist the trier of fact to understand the evidence or to determine a fact in issue” and “if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliable to the facts of the case.” Fed. R. Evid. 702. An expert's opinion must be based on (1) scientific methods, (2) known facts—not merely subjective belief or unsupported speculation, and (3) any inferences drawn from known facts must be based on good grounds. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993).

Hearsay is not admissible except as provided by the exceptions to the Rules. Fed. R. Evid. 802. A “statement” is defined as (1) an oral or written assertion or (2) nonverbal conduct of a person, if it is intended by the person as an assertion. Fed. R. Evid. 801(a). An exception to the hearsay rule is a “memorandum or record concerning a matter about which a witness once had

knowledge but now has insufficient recollection.... If admitted, [it] may be read into evidence but may not itself be received as an exhibit unless offered by an adverse party.” Fed. R. Evid. 803(5).

C. Same Arguments as in RCT's Motion in Limine 3

The Court has already entertained the same arguments present in this Motion and as per its ruling in the denial of RCT's Motion in Limine 3, it now GRANTS Microsoft's Motion in Limine.

IV. CONCLUSION

IT IS HEREBY ORDERED that Microsoft's Motion in Limine to Admit Comparison Images is GRANTED. (#958.)

All Citations

Not Reported in Fed. Supp., 2009 WL 10673979

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KeyCite Yellow Flag - Negative Treatment

Distinguished by [Jackson v. E-Z-GO Division of Textron, Inc.](#), W.D.Ky., July 23, 2018

2017 WL 1197755

United States District Court, D. New Jersey.

[Angela RUGGIERO](#), Plaintiff,

v.

YAMAHA MOTOR CORPORATION, U.S.A., Defendant.

Civil Action No. 15-49 (JBS/KMW)

|

Signed 03/31/2017

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OPINION

[JEROME B. SIMANDLE](#) Chief U.S. District Judge

I. INTRODUCTION

*1 In this products liability action, Plaintiff Angela Ruggiero (hereinafter, “Plaintiff”) alleges that Defendant Yamaha Motor Corporation, U.S.A. (hereinafter, “Defendant” or “Yamaha”) failed to provide adequate warnings when Plaintiff fell off a personal watercraft and sustained serious injuries. Defendant has moved to strike the reports and testimony of Plaintiff's expert William Kitzes, and asserts that without his report and testimony, Plaintiff has insufficient evidence for a reasonable jury to conclude Defendant is liable for a failure to warn claim.

For the reasons that follow, Defendant's motion to strike will be granted, and its motion for summary judgment will be denied.

II. BACKGROUND¹

A. Factual Background²

On June 30, 2012, Plaintiff suffered a severe rectal laceration when she fell off a 2009 Yamaha FZR WaveRunner personal watercraft (“FZR” or “PWC”) ³ just off of Brigantine Township Beach. (Def. Statement of Material Facts at ¶¶ 1, 3.) Plaintiff's boyfriend, Thomas Fimple was the owner and operator of the FZR at the time of the incident, with Plaintiff holding on behind him as a passenger. (Id. at ¶ 2.) As Mr. Fimple approached the beach, he accelerated his FZR towards a large boat producing a large wake. (Id. at ¶¶ 8–9.) Contrary to his usual practice of warning Plaintiff before he would accelerate his FZR (so Plaintiff could hold on), in this instance, Mr. Fimple did not advise Plaintiff that he was going to accelerate. (Id. at ¶¶ 10–11; Ruggiero Dep. 48:24–25–49:1–4.) As a result, Plaintiff did not hold on, fell off the vessel, and hurt her back. (Id. at ¶ 13.) Plaintiff

was wearing a two-piece bathing suit when the incident occurred, as she was not wearing a wetsuit bottom or other protective clothing at the time of her injury. (*Id.* at ¶¶ 4–5.)

Mr. Fimple purchased the FZR from Deptford Honda Yamaha on July 19, 2009 and had owned it for nearly three years at the time of the incident. (*Id.* at ¶ 15.) Defendant, the wholesaler, had originally sold the FZR to Deptford Honda Yamaha (*Id.*) Prior to the accident, Mr. Fimple had modified the FZR in a variety of ways to make it accelerate faster, while also installing a decorative decal wrap that covered all the original equipment warning labels on the FZR except for the Uniform Label located on the glove box door below the handlebars. (*Id.* at ¶¶ 16–17.) When he purchased the FZR, Mr. Fimple received the Owner's Manual, a Riding Practice Guide, a waterproof Riding Instructions Placard, and a thick plastic Ziploc bag to store the information. (*Id.* at ¶ 18.)

At the time of sale, Mr. Fimple's FZR had two warning labels affixed to the watercraft that specifically addressed the risk of orifice injuries and the need to wear protective clothing. These labels were located on the handlebars (on the lid of the glove box) and at the rear of the craft (next to the rear boarding deck). (*Id.* at ¶ 22.)

*2 The contents of these warning labels is not challenged by Plaintiff, only their placement on the watercraft. The label on the glove box (“Uniform Label”)⁴ specifically stated:

To reduce the risk of SEVERE INJURY or DEATH: ... WEAR PROTECTIVE CLOTHING. Severe internal injuries can occur if water is forced into body cavities as a result of falling into water or being near jet thrust nozzle. Normal swimwear does not adequately protect against forceful water entry into rectum or vagina. All riders must wear a wet suit bottom or clothing that provides equivalent protection (See Owners' Manual).

(*Id.* at ¶ 23.) Plaintiff never read this label. (Kitzes Dep. 19:9.) The second warning label, affixed behind the seats of the FZR above the boarding platform, states:

Severe internal injuries can occur if water is forced into body cavities as a result of being near jet thrust nozzle. Wear a wetsuit bottom or clothing that provides equivalent protection. Do not board PWC if operator is applying throttle.

(Def. SMF at ¶ 27.) Plaintiff testified she never read this label either because Mr. Fimple had covered it up with a decorative decal. (Kitzes Dep. 19:15–19.) Furthermore, the Owner's Manual instructs all riders to read the manual and warning labels before riding the PWC, and warnings about the potential risk of orifice injuries and the need to wear protective clothing are found on page 6, 7, 12, 61, 62, and 64 of the Owner's Manual. (*Id.* at ¶ 29–30.)

Plaintiff began riding as a passenger on Mr. Fimple's FZR in 2011, but Mr. Fimple never told her about the requirement to wear protective clothing as stated in the safety literature and on-product warnings that accompanied the FZR when he purchased it, nor did he ask her to review any of the materials or the on-product warnings on the craft, or to read the Owner's Manual. (*Id.* at ¶¶ 38–41.) Plaintiff also never read any of the warnings on the FZR, nor did she read any warning (on the product, in the product literature, or otherwise) for the FZR that discussed the risk of orifice injuries and how to avoid the risk (by wearing protective clothing). (*Id.* at ¶¶ 45–47.) In fact, Mr. Fimple has never reviewed the safety information for any PWC he has owned or used. (*Id.* at ¶ 51.) Mr. Fimple first learned to operate a PWC in 1993, and explained that “[e]verything that I've been taught, I've been taught through my uncle, who was a boater, my grandfather, who was a boater, my aunt, who is a boater, their entire lives. So

them teaching me physically how to properly do things, I didn't feel those warning labels would affect me at all because they've taught be all the safety I needed to know... And those warning labels, I just look at them and say that's something that I already probably know, and just kind of blow them off.” (*Id.* at ¶¶ 53, 58.)

B. Procedural Background

Plaintiff filed her Complaint against Defendant in the Superior Court of New Jersey, Burlington County, on June 23, 2014. [Docket Item 1.] Defendant properly removed the case to this Court under 28 U.S.C. § 1441(a). (*Id.*) Plaintiff's Complaint consists of four counts: (1) strict products liability against Defendant for design defect and failure to warn; (2) negligence against Defendant for inadequate instructions and warnings for the FZR; (3) a strict products liability claim identical to the First Count but directed against fictitious individuals, and (4) a negligence claim identical to the Second Count but directed against fictitious individuals.⁵ After pretrial discovery, Defendant filed this motion for summary judgment [Docket Item 24], which has been fully briefed. The Court held a *Daubert* hearing and oral argument on March 17, 2017. [Docket Item 31.]

III. STANDARD OF REVIEW

C. Summary Judgment Standard, Generally

*3 Summary judgment is appropriate if “there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law.” *Alabama v. North Carolina*, 560 U.S. 330, 344 (2010) (citations and internal quotation marks omitted); see also *FED. R. CIV. P. 56(a)*.

In evaluating Defendant's motion for summary judgment, the Court must view the material facts in the light most favorable to the non-moving party, Plaintiff, and make every reasonable inference in that party's favor. See *Scott v. Harris*, 550 U.S. 372, 378 (2007); *Halsey v. Pfeiffer*, 750 F.3d 273, 287 (3d Cir. 2014). An inference based upon “‘speculation or conjecture,’” however, “‘does not create a material factual dispute sufficient to defeat summary judgment.’” *Halsey*, 750 F.3d at 287 (citations omitted). Rather, the non-moving party must support each essential element with concrete record evidence. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986).

“Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party,” the Court may grant summary judgment. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

IV. DISCUSSION

A. Motion to Strike Expert Testimony of William Kitzes

The Court first addresses Defendant's motion to strike at the outset, as it impacts the outcome of Defendant's motion for summary judgment.⁶ In support of her theory of liability against Defendant, Plaintiff has produced the expert report, supplemental report and testimony of William F. Kitzes, J.D. (Pl. Statement of Additional Material Facts at ¶ 1.) Mr. Kitzes testified at his deposition that he has offered testimony in approximately eight other cases involving personal watercraft in his career, with two involving orifice injuries. (*Id.* at ¶ 12.) He has opined about the location of the warning on Mr. Fimple's PWC, that “an additional [third] label needed to be placed on the seat in front of the passenger so that they got directly the information they needed to protect themselves.” (*Id.* at ¶ 31.)⁷ In Mr. Kitzes' view, this “failure to provide an adequate warning in the location where it can be used by the person who needs it” is creates an “unreasonable risk of catastrophic injury, particular to women, under foreseeable conditions well-known to Yamaha for nearly 20 years.” (*Id.* at ¶ 25; Kitzes Dep. 47:17–20.) Plaintiff does not take issue with the actual wording of the two warnings on this watercraft, which are not at issue.

Defendant moves to exclude Mr. Kitzes' reports and testimony under *Daubert v. Merrill Dow Pharma., Inc.*, 509 U.S. 579 (1993) because (a) he is not qualified to express the opinion that he offers, (b) his opinion is not reliable, (c) his “method” to derive these opinions is not scientific, and (d) his generic views about warnings are not helpful to the jury. (Def. Br. at 1.)⁸

*4 Federal Rule of Evidence 702 “embodies a trilogy of restrictions on expert testimony: [1] qualification, [2] reliability, and [3] fit.” Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–43 (3d Cir. 1994)); see also FED. R. EVID. 702.

1. Qualifications

Defendant first attacks Mr. Kitzes' qualifications as an expert in the present matter. The qualification prong requires “that the witness possess specialized expertise.” Schneider v. Fried, 320 F.3d 396, 405 (3d Cir. 2003). The Third Circuit has “interpreted this requirement liberally,” holding that “a broad range of knowledge, skills, and training qualify an expert as such.” In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). The basis of “specialized knowledge” can be from “practical experience as well as academic training and credentials.” Kane Builders, Inc. v. Southern New Jersey Building Laborers Dist. Council, No., 2007 WL 2416470, at *6 (D.N.J. 2007) (quoting Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998)). The Third Circuit has interpreted the “specialized knowledge” requirement liberally, finding that “Rule 702's liberal policy of admissibility extends to the substantive as well as the formal qualifications of experts.” In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). “[I]f the expert meets the liberal, minimum qualifications then the level of the expert's expertise goes to credibility and weight, not admissibility.” Kannankeril v. Terminix Int'l Inc., 128 F.3d 802, 809 (3d Cir. 1997).

Mr. Kitzes received his bachelor's degree in history with a minor in political science from the University of Wisconsin and his law degree from the American University Washington College of law. (Def. SMF at ¶¶ 59–61; Kitzes Dep. 25:8–18.) After law school, he worked as an attorney at the Consumer Product Safety Commission, and after six years there, he joined the Institute for Safety Analysis as Vice President and General Manager. (Ex. C. to Opp'n.) For the last thirty-four years, Mr. Kitzes has worked at Consumer Safety Associates, a consulting company he founded that includes himself and his wife. (Kitzes Dep. 27:21–23.) He has spoken at dozens of seminars and workshops on safety-related issues, and has written a wide range of articles on consumer product safety. (Ex. C to Opp'n.) Several manufacturers, including Dick's Sporting Goods and a large vending machine company, have hired Mr. Kitzes over the years to consult on product safety issues, specifically regarding the development of on-product warning labels. (Id.)

Despite his experience, Mr. Kitzes has no degrees in engineering, psychology, communications theory, or any science field, nor does he have a degree in industrial safety management. (Def. SMF at ¶¶ 61–62.) Furthermore, Mr. Kitzes has never owned a PWC, has only ridden a PWC four times in his life, has not ridden a PWC in over ten years, and has never ridden the FZR model WaveRunner. (Def. SMF ¶¶ 63–66.) He did not visit the accident location, nor did he inspect the subject FZR or an exemplar FZR. (Id. at ¶¶ 67–68.) He also did not personally speak with Plaintiff, Mr. Fimple, or Mr. Chiaradonna (Mr. Fimple's friend who accompanied them that day) to discuss the accident. (Id. at ¶ 70.)

*5 Plaintiff claims that Mr. Kitzes is “eminently qualified to testify regarding products safety warnings based on the knowledge, skill, and training he has acquired over the course of his 30 year career in safety management consulting,” as he has “specialized expertise regarding products safety warnings based on his knowledge of safety management literature and standards and his years of work in consulting.” (Opp'n at 24.) As such, he has knowledge that is superior to the average layman in regards to warnings. On the other hand, Defendant argues that “[w]ith no education or training in PWC design or operation, or human factors engineering, Mr. Kitzes is not qualified to opine on the efficacy of on-product warning labels on the FZR or alternate warning systems.” (Def. Br. at 20.)⁹

The Court finds that Mr. Kitzes has at least the minimum of education, training, and experience to testify about warning labels generally. Despite the above deficiencies, exclusion of an expert witness on grounds of qualifications alone is “improper simply because an expert does not have the most appropriate degree of training.” Yarchak v. Trek Bicycle Corp., 208 F. Supp. 2d 470, 495 (D.N.J. 2002) (citing Diaz v. Johnson Matthey, Inc., 893 F. Supp. 358, 372 (D.N.J. 1995)). The fact that Mr. Kitzes is not a “human factors” expert does not mean that there is no “specialized knowledge” he can provide to inform Plaintiff's

allegations that the PWC warnings were inadequate due to their location on the PWC. See Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996) (“[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.”). Given the liberal construction of the qualifications of a putative expert under Daubert in the Third Circuit, see Yarchak, 208 F. Supp. 2d at 495 (observing same). Construing Mr. Kitzes' experience and education “liberally,” his “generalized qualifications” satisfy the requirement of expertise for the purposes of this case—the location of warnings. See Paoli, 35 F.3d at 741.

2. Reliability of Methodology

Absence of a methodology, on the other hand, presents a grave problem. In arguing that Mr. Kitzes' reports and testimony must be excluded, Defendant maintains that Mr. Kitzes utilized no methodology whatsoever in producing his reports. The reliability prong inquiries whether the expert's conclusion rests upon “the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’” Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993)); see also Kemly v. Werner Co., 151 F. Supp. 3d 496, 502 (D.N.J. 2015) (describing the same analytical framework); Krys v. Aaron, 112 F. Supp. 3d 181, 189–90 (D.N.J. 2015) (same).¹⁰ “[T]he standard for determining reliability is not that high, even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702.” In re TMI Litigation, 193 F.3d 613, 665 (3d Cir. 1999). Reliability, however, does not require the proffering party to demonstrate the “correctness” of the expert opinion. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994) (concluding that the “evidentiary requirement of reliability” amounts to a lower burden “than the merits standard of correctness”). Indeed, so “long as an expert's scientific testimony rests upon good grounds ... it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.” United States v. Marshall, 365 F.3d 215, 244 (3d Cir. 2004) (citations omitted) (emphasis added).¹¹

*6 In certain circumstances, admissible expert testimony may derive from an expert's knowledge and experience. Oddi v. Ford Motor Co., 234 F.3d 136, 158 (3d Cir. 2000). Kumho addressed the applicability of Daubert to non-scientific experts. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999) In non-scientific cases, such as here, the Daubert factors “may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's expertise, and the subject of his testimony.” Kumho, 526 U.S. at 150. Thus, “the relevant reliability concerns may focus upon personal knowledge or experience.” Id. at 152. The objective of Daubert's gatekeeping role, however—“to ensure the reliability and relevancy of expert testimony”—remains unchanged. Id. In any case, the district court enjoys “considerable discretion” to “determine the criteria for judging reliability under the particular circumstances.” Betterbox Communications Ltd. v. BB Technologies, Inc., 300 F.3d 325, 329 (3d Cir. 2002). “If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.” Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702. However, as the Supreme Court observed in Daubert, “vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” Daubert, 509 U.S. at 596.

Additionally, there are several additional “indicia of reliability” that have particular relevance in a failure to warn case such as this, including: (1) federal design and performance standards; (2) standards established by independent organizations; (3) relevant literature; (4) evidence of industry practice; (5) product design and accident history; (6) whether the expert uses illustrative charts and diagrams; (7) data from scientific testing; (8) the feasibility of the suggested modification, and (9) the risk-utility of the suggested modification. Milanowicz v. The Raymond Corp., 148 F. Supp. 2d 525, 532–536 (D.N.J. 2001).¹²

Defendant argues that Mr. Kitzes' testimony is not reliable because it lacks a basis in sound principles, evidence, and methodology. Specifically, Defendant argues that Mr. Kitzes' “untested theory that a third orifice injury warning must be placed

on the seat has no support in data or authoritative scientific literature or studies.” (Reply Br. at 9.) Furthermore, Mr. Kitizes “offers no evidence regarding the relative likelihood of a PWC rider to read a warning label placed on the seat of the craft, as opposed to those on the glove box directly in front of the operator or above the aft deck.” (Def. Br. at 22.)¹³

Plaintiff responds that Mr. Kitizes “cites to articles and medical literature establishing the chronology of when Yamaha first became aware of the potential for orifice injuries resulting from passengers falling off of personal watercraft,” while he also cites “to the applicable ... standards and criticiz[ing] YMUS based on their failure to comport with those standards.” (Opp’n at 31–32.) Mr. Kitizes bases his opinion on location of the warnings primarily on the voluntary American National Standards Institute (ANSI) Z535.4 Standard for Product Safety Signs and Labels. Specifically, Section 9 of the ANSI Standards addresses sign and label placement. It states:

9.1 Location: Product safety signs and labels shall be placed such that they will: (1) be readily visible to the intended viewer and (2) alert the viewer to the potential hazard in time to take appropriate action.

*7 (Kitizes Report at 14.) Mr. Kitizes argues that Defendant’s labeling on the PWC at issue fails to comply with this standard because the front label is not “readily visible to the intended viewer,” here, the passenger, and the warning label on the aft portion beneath the seat may not be noticed by a passenger who mounts the PWC from the side, as Plaintiff did in this instance.

The Court finds that Mr. Kitizes’ conclusion regarding the location of the warning is not based upon any sufficiently reliable methodology under [Blue 702](#). The problem with his conclusion is that in developing it, he failed to perform any tests or focus groups, take any measurements, rely on any articles on location of warnings (besides the very generalized ANSI standard itself), conduct any reenactments or even examine the PWC itself, leaving his conclusion to be, at best, an educated guess. Speculation is not methodology. Completing any of the above actions would have shed light on whether warning on the seat would have made a difference in Ms. Ruggiero’s conduct on the day of the accident. (Kitizes Dep. 74:3–7.)¹⁴

More specifically, Mr. Kitizes criticizes the placement of two otherwise adequate warning labels on this small watercraft by speculating that the passenger would not be able to notice either of these labels during normal use. The total distance from the front handlebar (where the driver steers the PWC) to the back of the passenger seat directly behind the driver is only 39 inches. The passenger typically rides by holding on to the driver, sitting forward in the rear seat. The passenger’s head is thus well less than 39 inches from the front warning label. With no measurements or reconstruction, it is guesswork whether a passenger would be apt to notice the front label while riding. Similarly, Mr. Kitizes applied no methodology to support his presumption that a passenger boarding from the side of the craft would not see the front label or the rear label. The rear label is positioned where a passenger will see it when boarding from the water using the aft platform, and the seat support itself slants forward so that even a passenger getting on or off from the side may see the warning label from above the seat. Mr. Kitizes takes none of these physical facts into account in speculating that the rear label placement is not visible to a passenger. Where the only criticism of Defendant’s warning label system is the placement, rather than the content or prominence of the labels, the lack of an expert methodology for determining the adequacy of placement becomes a fatal shortcoming of the proffered opinion.

*8 Moreover, Mr. Kitizes’ opinions about the location of the warnings are based on examining one portion of a voluntary industry standard, as opposed to the peer-reviewed warning system (the Uniform Label) developed in 1999 by experts in the PWC industry, regulators in the recreational boating field, and the organizations promulgating industry standards. (Def. Br. at 22.) Mr. Kitizes claims that no elaborate testing needed to be done here, but without any testing at all, his opinion is just speculation. Mr. Kitizes’ “methodology” of reviewing photographs and relying on a voluntary generalized industry standard that proclaims that warning labels should be placed where they are readily visible to the intended user does not pass muster under Daubert and Kumho.

In Masterson v. BJ Stores, No. 03–3202, 2007 WL 6560686 (D.N.J. Mar. 20, 2007), a failure to warn case involving a plaintiff who injured herself riding a bodyboard, the Court excluded Mr. Kitzes' testimony on reliability grounds because he admitted that he “failed to test the effectiveness of such a warning or point to industry practice at the time the bodyboard was manufactured.” (*Id.* at 14.) As a result, the court held that Mr. Kitzes' opinions were “extremely questionable” and not reliable under Daubert. The court explained that “Kitzes' methodology would seem to only support his conclusions on how [Defendant] should have performed and maintained a product safety management program.” (*Id.* at 16.); see also S.S. Leatt Corp., No. 12–483, 2013 WL 3714142, at *18 (N.D. Oh. July 15, 2013) (“Even acknowledging that Kitzes has expertise in the field of ‘product safety management’ and that such expertise is or could be relevant to some issue or issues raised in the case, there is insufficient information and analysis in Kitzes's report to conclude that Kitzes employed a ‘reliable’ methodology in reaching his ‘conclusions’ such that his opinions are admissible.”). Similarly, here, Mr. Kitzes has not tested whether a warning on the passenger seat would be more effective than the warnings in the front and the rear, nor could he point to any manufacturer who put a warning on the passenger seat at the time of the accident.¹⁵

The Court also finds Hickerson v. Yamaha Motor Corp., U.S.A., No. 13–2311, 2016 WL 4367141 (D.S.C. Aug. 16, 2016) to be persuasive regarding the reliability of Mr. Kitzes' “move-it-to-the-seat” opinion. There, in a similar fact pattern to the instant case, Plaintiff, wearing a two-piece bathing suit and not a wetsuit, rode as a passenger on a PWC and fell off, sustaining serious injuries. Hickerson, 2016 WL 4367141 at *1. There were two warnings on the PWC, one below the handlebars in front of the PWC's operator, and another toward the rear of the PWC, but Plaintiff did not read either warning. *Id.* Plaintiff brought a failure to warn suit against Yamaha, and supported her claim with expert testimony from Dr. Anand Kasbekar, who opined that “the warnings and instructions used by defendants are inadequate and insufficient given the potential for extremely serious injuries.” *Id.* at *3. Dr. Kasbekar proposed that an additional warning should have been placed on the passenger seat, but the court excluded his testimony “due to its unreliability under the standards of Fed. R. Evid. 702,” since he had “not tested his proposed alternative warning system,” and that “he provides no specific relevant research or studies ... on which he relies.” *Id.*

*9 Defendant argues that here, as in Hickerson, Mr. Kitzes' theory that a third warning of the need to wear protective bottoms to prevent orifice injury must be placed on the seat has no support in data or authoritative scientific literature or studies. (Reply Br. at 9.) Plaintiff argues that Hickerson is inapposite because that court's ruling on the admissibility of expert testimony “actually supports” Plaintiff's position since the court found Dr. Kasbekar “qualified as an expert” and that unlike Dr. Kasbekar, Mr. Kitzes “has authored many warnings from start to finish that would be ready to be placed on a product and has written a peer reviewed article on warnings.” (Opp'n at 41–42, 44). Here, while Mr. Kitzes relies on an ANSI standard to opine on the placement of the warning location, he has failed to articulate his methodology supporting how he arrived at the conclusion that a passenger seat warning is “readily visible” under the standard, and how the existing front and rear warning system falls short. He provides no reason why his conclusion is not simply *ipse dixit*. As a result, the Court finds that Mr. Kitzes' reports and testimony are unreliable. While the analysis could stop here, for the sake of completeness, the “fit” prong is Daubert is briefly examined below.

3. Fit

Finally, the “fit” requirement is based upon the text of Rule 702, which requires that an “expert's scientific, technical or other specialized knowledge... help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a). To be helpful, expert testimony must be “sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.” United States v. Schiff, 602 F.3d 152, 173 (3d Cir. 2010)(quotation marks and citation omitted). Conversely, “expert evidence which does not relate to an issue in the case is not helpful.” United States v. Ford, 481 F.3d 215, 219 n.6 (3d Cir. 2007) (quotation marks and citation omitted). “The standard is not that high, ‘but is higher than bare relevance.’ ” Schiff, 602 F.3d at 173 (citation omitted).

Plaintiff argues that Mr. Kitzes' report and testimony “succinctly informs” where Defendant “has fallen short in its attempt to warn the public, and female passengers in particular, about the potential for these horrific injuries”; as a result, Mr. Kitzes' testimony “will assist the trier of fact in understanding plaintiff's position that the orifice warning needs to be conspicuous and

on the seat where a passenger such as Ms. Ruggiero has an opportunity to read it and heed its message.” (Opp’n at 38.) But Mr. Kitzes’ testimony focuses more on the general industry standards and the history of such standards, and is not sufficiently tied to the facts of this case, *i.e.*, whether or not Ms. Ruggiero would have seen this passenger seat warning, as well as why the Defendant’s labeling system would not have been “readily visible” to a passenger, as the ANSI standard states. Mr. Kitzes’ opinion that the labels are not visible to the passenger is not grounded to the actual watercraft at issue here, which he never examined or measured. Mr. Kitzes’ proposed testimony simply does not fit the actual warning label system in this case. A lay juror would be in as good, or perhaps better, position to determine this issue of fact, aided by actual measurements or observations, of the PWC at trial, as discussed in Part IV.B, below.

For all of these reasons, Yamaha’s motion to exclude Mr. Kitzes’s opinion on admissibility grounds under [Federal Rule of Evidence 702](#) will be granted.

B. Need of Expert Testimony

Plaintiff argues that even without Mr. Kitzes’ testimony, she can still prove her claim of failure to warn because the allegations of negligence against Defendant are “simple” and a “juror who possesses average judgment and experience does not need expert testimony to understand that a warning on a product must be conspicuous and must be placed in a location where the user of the product intended to be warned can see it.” (Opp’n at 40.) On the other hand, Defendant argues that the FZR is a complex instrumentality and that the “adequacy of the FZR’s warnings system and the need for alternative warnings require application of specialized knowledge in human factors engineering, the use, operation, and transportation of the PWC, the development and testing of the Uniform Label, and applicable warning standards, all of which are beyond the ken of an average juror.” (Reply Br. at 9.) The Court tends to agree with Plaintiff, as now discussed.

***10** A plaintiff may prove the existence of a product defect by relying on the testimony of an expert, or alternatively, a plaintiff may proffer circumstantial evidence of a defect, including use, handling, and operation of the product. [Lauder v. Teaneck Volunteer Ambulance Corps.](#), 368 N.J. Super 320, 331 (App Div. 2004). However, expert testimony is required in a warning defect case where the subject matter “falls outside of the common knowledge of the factfinder and depends on scientific, technical, or other specialized knowledge.” [Jerista v. Murray](#), 883 A.2d 350, 364 (N.J. 2005); *see also* [Butler v. Acme Mkts., Inc.](#), 445 A.3d 1141, 1147 (N.J. 1982) (stating that expert testimony is necessary where “the matter to be dealt with is so esoteric that jurors of common judgment and experience cannot form a valid judgment”); [Macri v. Ames McDonough Co.](#), 211 N.J. Super. 636, 642 (App. Div. 1986) (requiring expert testimony where subject matter is such that jurors of common judgment and experience cannot “make a determination without the benefit of the information and opinions possessed by a person with specialized knowledge”). Where an “average juror can deduce what happened without resort to scientific or technical knowledge, expert testimony is not mandated.” [Jerista](#), 883 A.2d at 365.

The Court finds that Plaintiff can proceed without expert testimony in this case. While the PWC itself is certainly a complex instrumentality, here, given that the contents of the warnings are not at issue, it is not necessarily beyond the common knowledge of an average juror to determine whether the placements of the warnings were reasonably visible to a passenger using the PWC. The jury can observe at trial what warnings are visible on the PWC and what warnings are not, and Plaintiff can utilize eyewitness testimony. The limited issue of visibility therefore does not require expert testimony. This does not preclude Defendant from offering such testimony of qualified experts who have used a reliable methodology pertaining to this PWC or a prototype thereof.

C. Summary Judgment is Not Appropriate

Defendant argues that Plaintiff’s failure-to-warn claim independently fails on summary judgment because Plaintiff cannot prove that inadequate warnings proximately caused the damages where she chose not to read the warnings. (Def. Br. at 28.) Plaintiff responds that what is actually relevant is “what plaintiff would have done if she saw and read a label warning of the potential for orifice injuries prior to this accident.” (Opp’n at 47.)

A cause of action for failure to warn is governed by the New Jersey Products Liability Act (“PLA”), N.J.S.A. 2A:58C–1 *et seq.*¹⁶ Under Section 2 of the PLA, a plaintiff can prove that a product was defective if:

the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it ... failed to contain adequate warnings or instructions.

Id. at 2A:58C–2. In a failure-to-warn claim, the defect consists of the absence of an adequate warning concerning the product's potential for injury, and the plaintiff must prove that the warning's absence was the proximate cause of the harm. *Coffman v. Keene Corp.*, 628 A.2d 710, 716 (N.J. 1993). A manufacturer is not liable, however, where an adequate warning is provided. N.J.S.A. 2A:58C–4; *London v. Lederle Labs.*, 290 N.J. Super. 318, 327 (App. Div. 1996).

1. Adequate Warning

The PLA provides that “[i]n any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. N.J.S.A. 2A:58C–4. An adequate warning is defined as “one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger... taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used.” *Id.*; see also *Port Auth. of N.Y. and N.J. v. Arcadian Corp.*, 189 F.3d 305, 319 (3d Cir. 1999) (noting that the adequacy of the warning is determined in part by “taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used”); *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 491 (3d Cir. 1991) (explaining that the PLA “adopts an objective negligence standard in defining an adequate warnings”)(citations omitted). Warnings may be included in printed materials packaged with the product or on labels affixed to the product. They may be in words or pictures, and “pictorial symbols, rather than simply words, may be required to adequately convey safety warnings to some anticipated users.” *Levey v. Yamaha Motor Corp.*, 361 N.J. Super. 312, 318 (App. Div. 2003). The form they take is dictated by all of the circumstances, and the adequacy of the chosen form is generally a question for the jury. *Id.*; see *Perlman v. Virtua Health, Inc.*, No. 01–651, 2005 WL 1038953, at *4 (D.N.J. May 3, 2005)(explaining that the adequacy of a product warning is a jury question); *Grier v. Cochran Western Corp.*, 308 N.J. Super 308, 317 (App Div. 1998)(same).

*11 The Court finds that that there is a genuine dispute of material fact as to whether or not the two existing warnings on the PWC were adequate. Plaintiff testified that she did not read the front warning and “wasn't aware” of its existence under the handlebar. (Ruggiero Dep. 56:9–16.) She also testified that she never read the warning on the back of the PWC prior to or after her injury.¹⁷ (*Id.* 62:8–17.) Furthermore, Plaintiff testified that she has never operated a PWC, that she has only been a passenger every time she has ridden a PWC, and that when she boarded the day of the accident, Mr. Fimple was already on the vessel. (*Id.* at 31:6–21; 46:7–14.) Plaintiff also never sat on the PWC alone. (*Id.* at 45:10–11.) Plaintiff also points to the testimony of Defendant's expert Robert K. Taylor, P.E., who stated that “I would agree that once a passenger is seated on the craft behind the operator, it would be difficult to read a label in front of the handlebars or at the stern underneath the grabhandle.” (Ex. F. to Opp'n at 27.)¹⁸ Mr. Taylor, when asked if “when the passenger sits down that label may well be blocked by the operator,” replied “[a]t that particular point in time that may be true.” (Taylor Dep. at 52:7–15.) Certainly whether a displayed warning would catch the attention of a reasonably prudent passenger would contribute to the warning adequacy analysis. As explained *infra*, the jury will be able to look at, in a common sense way, whether the warnings were visible and in a location where a reasonably typical passenger could see them.

2. Proximate Causation

Regarding causation, Defendant argues that even assuming its warnings were inadequate, its warnings were not the proximate cause of Plaintiff's injury. In failure to warn cases, New Jersey has adopted a rebuttable "heeding presumption," affording a plaintiff "the use of the presumption that he or she would have followed an adequate warning had one been provided." [Coffman v. Keene Corp.](#), 133 N.J. 581, 603 (1993); see also [Mohr v. Yamaha Motor Co., Ltd.](#), 2013 WL 3762719 (App. Div. 2013).¹⁹ When the claim is a failure to warn, the heeding presumption applies to shift the burden of production of evidence to the defendant. [Coffman](#), 133 N.J. at 603. The defendant must come forward with evidence such as "the plaintiff's knowledge of the very risk that the absent warning was supposed to address," or of "plaintiff's attitudes and conduct apart from knowledge of the product's risk" [Sharpe v. Bestop](#), 314 N.J. Super. 54, 74 (App. Div. 1998); see also [id.](#) at 77 (noting that it is "consistent with our evidence rules" that a defendant "may only introduce rebuttal evidence of a plaintiff's failure to heed warnings if such evidence rises to the level of habit or routine practice").

At the outset, the Court has found no case in New Jersey (or applying New Jersey law) where the heeding presumption was utilized when there was already an existing warning on the product, let alone two warnings, as in this case. But assuming that the court adopts the heeding presumption, Defendant has offered evidence, from Plaintiff's deposition, where Plaintiff states that it never occurred to her that she ought to have read the labels on the PWC to see what the warnings were about. (Ruggiero Dep. 71:25 – 72:7). Defendant argues that Plaintiff cannot establish proximate causation and the heeding presumption is therefore rebutted because neither Plaintiff nor Mr. Fimple read, or ever thought they should read, any of the warning labels on the PWC. ([Id.](#); Fimple Dep. 45:7 to 46:3.) In other words, Defendant contends there is no evidence that had there been a warning on the passenger seat, that Plaintiff would have read and heeded it. See [Coffman](#), 133 N.J. at 602–03; see also [Hickerson](#), 2016 WL 4367141, at *4–*5 ("[T]he plain language of the multiple warnings, both near the front and rear part of the PWC ... reasonably advise anyone who rides the PWC, including a passenger, of the very types of dangers Plaintiff endured and moreover provides specific recommendations to prevent such injuries ... the evidence does not clearly support that a more adequate warning would have mattered anyway—that is, that the inadequate warnings caused her injuries.").

*12 However, Plaintiff, upon being asked the question: "[a]nd, was it your habit, before June of 2012, that when you saw there was a sign that said warning, that you would read those instructions so you can see exactly what it was that either the manufacturer of the product or the company or the people who placed that warning in there was trying to convey to you," responded that "[she] would look at it." (Ruggiero Dep. 54:7–16.)²⁰ Further, she testified that she "wasn't aware" of the warning label in the front of the PWC, and presumably was not aware of the warning label in the back because Mr. Fimple covered it with a decal. ([Id.](#) at 56:13–16.) There is no evidence in the record that Ms. Ruggiero was aware of the risks of using a PWC, and there is no evidence that she ignored any warnings. Compare [Scrofani v. Stihl Inc.](#), 44 Fed.Appx. 559, 563 (3d Cir. 2002) (affirming the entry of summary judgment for defendant because plaintiff "acted in direct contravention of numerous warnings contained therein" and that "[t]his disregard of existing warnings demonstrates that [plaintiff] would have ignored the most perfect of warnings"); [Hickerson](#), 2016 WL 4367141, at *5 (noting that "the evidence does not clearly support that a more adequate warning would have mattered anyway"). As a result, the Court finds that after a review of Defendant's rebuttal evidence, reasonable minds could differ as to whether an adequate warning, if given, would have been read and heeded by the plaintiff. At the very least, this presents the jury an opportunity to conclude that Plaintiff would have, in response to an adequate warning, done something differently. Thus, a genuine issue of material fact remains for trial.

V. CONCLUSION

In sum, Defendant's motion to strike the reports and proposed testimony of William Kitzes will be granted, and Defendant's motion for summary judgment will be denied. The accompanying Order will be entered.

All Citations

Not Reported in Fed. Supp., 2017 WL 1197755, Prod.Liab.Rep. (CCH) P 20,048

Footnotes

- 1 The Court has diversity jurisdiction over this action pursuant to [28 U.S.C. § 1332](#).
- 2 The Court distills this undisputed version of events from the parties' statements of material facts, affidavits, and exhibits, and recounts them in the manner most favorable to Plaintiff, as the party opposing summary judgment.
- 3 The 2009 Yamaha FZR WaveRunner is a two-person, water jet-propelled, recreational boat. (Def. SMF at ¶ 16.)
- 4 The Uniform Label is used by every PWC manufacturer in the United States. (Def. SMF at ¶ 24.)
- 5 The parties agree that Plaintiff has now confined this action to a failure-to-warn theory only. (Opp'n at 18.)
- 6 The parties dispute whether expert testimony is actually needed in this case. See infra Part IV.B.
- 7 Regarding the color of the warning, Mr. Kitzes has also opined that the safety warnings were inadequate because the Uniform Label on the glove box of the FZR uses white letters on a black background instead of black letters on a white background. (Ex. 19 to Def. Br. at 49:10 to 50:8.) Plaintiff withdrew this opinion at the Daubert hearing, so the Court will only address Mr. Kitzes' opinion regarding the location of the warning.
- 8 An expert in a products liability case offered to testify regarding inadequate warnings must meet the Daubert criteria. Milanowicz v. Raymond Corp., 148 F. Supp. 2d 525, 541 (D.N.J. 2001).
- 9 Human factors engineering "is concerned with an evaluation of the human factors that are involved in the design and use of products, equipment, and facilities." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 322 n.10 (3d Cir. 2003).
- 10 Where the reliability turns upon the intricacies of an expert's scientific technique, Daubert (and its progeny) directs courts to undertake an inquiry, in essence, into whether the disputed technique has gained acceptance in the relevant scientific community. See In re Paoli, 35 F.3d at 742 n.8 (listing the relevant factors). These "specific factors neither necessarily nor exclusively applies to all experts," Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999); see also Kannakeril v. Terminix Int'l, Inc., 128 F.3d 802, 806–07 (3d Cir. 1997) (same).
- 11 In assessing the reliability of an expert's methodology under Daubert, the trial court can consider various factors, including: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subjected to peer review; (3) the known or potential rate of error, (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. In Re Paoli, 35 F.3d at 742.
- 12 In addition to the general reliability criteria of Daubert, in a warnings case, where an expert proposes alternate warnings, he should at least either test the effectiveness of those warnings or point to contemporaneous industry practice. Otherwise, the reliability of the expert's testimony on the proposed warning is "extremely questionable." Milanowicz, 148 F. Supp. 2d at 541 (citation omitted).

- 13 The Court also finds that Mr. Kitzes' testimony in [Colombo v. BRP US Inc.](#), 230 Cal.App.4th 1442 (4th Dist. 2014) makes his opinion in this case unreliable. There, defendant did not have a second on-product warning label on the rear of the craft, and Mr. Kitzes called having a label there “a superior location and it's a superior concept.” (Ex. 2 to Reply Br.)
- 14 Mr. Kitzes stated at the [Daubert](#) hearing that he did not need to leave his house to have a reliable methodology for his opinion, as he looked at photographs of the PWC to determine the proper placement of the warning label. But Defendant's expert, Robert K. Taylor, P.E., in addition to reviewing the deposition transcripts and photographs like Mr. Kitzes did, also completed “on-water testing of an exemplar PWC, [reviewed] surrogate video demonstrations with an exemplar PWC, inspect[ed] the subject PWC and trailer, and inspect[ed] the launch sites used to launch the subject PWC.” (Taylor Report at 2.) Further, another one of Defendant's experts, Kevin Breen, examined the subject PWC, the incident site, and an exemplar PWC that he “utilized for various operational and human factors evaluations.” (Breen Report at 6.)
- 15 Plaintiff points out that the recently-released 2016 Kawasaki Jet Ski has a label on the passenger seat, which demonstrates feasibility. (Opp'n at 36–37; Reply Br. at 8.) But the court in [Masterson](#) held that “[o]n its own, the warning that post-dates the purchases of the bodyboard at issue here cannot be relied upon to demonstrate what [Defendant] knew or should have known the year prior.” [Masterson](#), 2007 WL 6560686 at 15. As a result, Mr. Kitzes cannot rely on the Kawasaki design as part of his methodology in this case, as it is not relevant.
- 16 This statutory standard for determining the adequacy of a product safety warning is essentially a codification of the common law standard. [Grier v. Cochran W. Corp.](#), 308 N.J. Super. 308, 317 (App Div. 1998).
- 17 The parties dispute whether Plaintiff actually saw or should have seen the front and rear warnings, which cannot be resolved on this summary judgment motion.
- 18 Mr. Taylor also opined that “[t]he appropriate time to learn of potential hazards and protective measures is well before you are seated on the PWC and engaged in riding.” (Ex. F. to Opp'n at 27.)
- 19 The heeding presumption “serves to reinforce the basic duty to warn – to encourage manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings.” [Coffman](#), 133 N.J. at 599. As one court has explained, “the heeding presumption was adopted for the express purpose of making a plaintiff's burden less onerous on the issue of proximate cause with respect to a product warning.” [Perlman](#), 2005 WL 1038953, at *5.
- 20 Additionally, the following exchange occurred during Plaintiff's deposition:

Q: Is it your habit—or was it your habit before June 30th, 2012, to read warnings and follow them?

A: If I see a warning, I read it.

Q: And follow it?

A: I follow it, just like I wear a seat belt every day when I drive.

(Ruggiero Dep. 142:12–18).

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United States District Court, D. New Jersey.

Theresa CHRISTOFORETTI, Plaintiff,

v.

BALLY'S PARK PLACE, INC. d/b/a Bally's Atlantic City, et al., Defendants.

CIVIL ACTION NO. 12-4687

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Signed August 30, 2021

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OPINION

Slomsky, District Judge

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I. INTRODUCTION

On August 4, 2010, seventy-year-old Plaintiff Theresa Christoforetti traveled with friends to Atlantic City, New Jersey. (See Doc. No. 71-1 ¶ 2.) After visiting several establishments, Plaintiff separated from the group and approached the east entrance of Bally's Wild, Wild, West Casino. (See *id.* ¶ 4.) As she approached the entrance, she stepped to her right to avoid other patrons exiting the casino, and she did not notice anything on the ground. (See *id.* ¶¶ 5, 8.) She alleges, however, that either human or animal feces was on the ground where she stepped, causing her to slip and fall. (See *id.* ¶ 5; Doc. No. 72 ¶ 7.) As a result, Plaintiff suffered a right ankle fracture, mental pain, and surgical expenses. (See Doc. Nos. 1 ¶ 6; 72 ¶ 13.)

On July 27, 2012, Plaintiff filed this action against Bally's Park Place d/b/a Bally's Atlantic City (“Defendant”). (Doc. No. 1.) In the Complaint, Plaintiff alleges that Bally's was negligent in causing her injuries. (See *id.* ¶ 5.) On August 22, 2019, Defendant filed the instant Motion to Bar the Opinions of Plaintiff's Liability Expert and for Summary Judgment, seeking a grant of summary judgment and to bar the testimony of R. Britton Colbert, CHA,¹ whom Plaintiff intends to call as an expert witness, from testifying at trial. (Doc. No. 71.) In the Motion, Defendant seeks to preclude Colbert's testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. (See *id.* at 9-22.) Defendant also moves for summary judgment, contending that Plaintiff's negligence claim fails as a matter of law. (See *id.* at 22-40.)

The Motion is now ripe for disposition. For reasons that follow, the Court finds that Colbert is permitted to testify as an expert on the hotel and lodging industry. Furthermore, there are genuine disputes of material fact concerning whether Defendant owned the property where Plaintiff allegedly fell. Accordingly, the Court will deny Defendant's Motion to Bar Plaintiff's Liability Expert and for Summary Judgment.

II. BACKGROUND

A. The August 4, 2010 Incident

*2 Defendant Bally's Park Place d/b/a Bally's Atlantic City is part of Caesar's Entertainment Group and is operated by Bally's Park Place, Inc. d/b/a Bally's Atlantic City (“Bally's”). (See Doc. No. 71-3 at 39.) Bally's property includes Bally's Wild, Wild, West Casino (the “Casino”), which has storefront property abutting the Boardwalk in Atlantic City, New Jersey. (See *id.*) The Boardwalk is a walkway of wooden boards that extends parallel to the Atlantic Ocean coastline.

On Wednesday, August 4, 2010, Plaintiff Theresa Christoforetti, who was seventy years of age at the time, and her friends traveled to Atlantic City. (See Doc. No. 71-1 ¶ 2.) The group spent the day eating, drinking, and gambling at various restaurants and casinos along the Boardwalk. (See *id.* ¶¶ 2-3.) At approximately 4:30 p.m., while walking along the Boardwalk, the group passed by Defendant's Casino, and Plaintiff diverted from her friends to gamble inside. (See *id.* ¶ 4.)

After leaving her friends, Plaintiff approached the Casino's east entrance, which is angular to, and not flush with, the Boardwalk's border.² (See id.; Doc. No. 72, Exs. C, E.) As Plaintiff approached the entrance, she noticed other Bally's patrons exiting from the left door, so she stepped to her right to enter through the right entrance. (See Doc. No. 71-1 ¶ 5.) When she stepped aside, Plaintiff did not see anything on the ground; however, human or animal excrement was on the ground outside the right entrance, which Plaintiff stepped on, causing her to slip and fall. (See id. ¶¶ 5, 8; Doc. No. 72 ¶ 7.) As a result of her fall, Plaintiff suffered a right ankle injury that required her to undergo surgery. (See Doc. No. 72, Ex. F.) Due to the accident, she claims to have suffered physical and mental pain, lost wages, and medical expenses. (See Doc. No. 1 ¶ 6.)

Defendant's closed-circuit television ("CCTV") surveillance footage captured the incident on video. (See Doc. No. 72 ¶ 16.) The footage shows that in the thirty minutes prior to the incident, no Bally's employees were seen inspecting or cleaning the Casino's east entrance. (See id. ¶ 19.) In addition, the footage shows Plaintiff's fall and Bally's security personnel responding to the scene. (See id. ¶ 21; Doc. No. 71-1 ¶ 12.) Later on, Bally's security personnel prepared an incident report, took photographs, and cleaned up the remaining debris. (Id.)

B. The Report and Deposition of R. Britton Colbert, CHA

Plaintiff hired a liability expert, R. Britton Colbert, CHA, who authored a report evaluating the standard of care and Defendant's duty of care in this case. (See Doc. No. 71-3 at 39.) Colbert has a Bachelor of Science in Business Administration from University of Denver's School of Hotel and Restaurant Management. (See id. at 51.) Additionally, he has worked in operations and corporate hotel management for over thirty years and has been certified for over twenty-one years as a Hotel Administrator by the American Hotel & Lodging Association. (See Doc. No. 72 at 221.) He also maintains his own consulting business that specializes in operating standards, property control, and premises liability. (See id.)

On December 12, 2018, the parties took Colbert's deposition. (See Doc. No. 71-3 at 54.) In his report and deposition, Colbert references the American Hotel and Lodging Association's publication Security and Loss Prevention Management, which he uses to opine on industry standards in hotel and lodging management. (See id. at 43; Doc. No. 72 at 224.) Based on that publication and his experience, he testifies that "it is customary and highly important daily practice in the hotel and lodging industry to properly and thoroughly inspect the lodging premises for hazards and other potential safety concerns or threats which could cause injuries to individuals on the property." (Doc. No. 71-3 at 45.) He also cites to a publication titled Hotel & Motel Management, which notes that the industry standard is for inspections to be done "as often as is reasonable in light of frequency and use." (Id.) Based on this information, Colbert concludes that Bally's owed their patrons, such as Plaintiff, a duty to use reasonable care to keep the premises in a reasonably safe condition. (See id.)

C. Procedural History

*3 On July 27, 2012, Plaintiff Christoforetti filed this action in the United States District Court for the District of New Jersey. (Doc. No. 1.) In the Complaint, Plaintiff alleges that Bally's owned and negligently operated the area where Plaintiff slipped, and that their negligence caused her injuries. (See id. ¶ 5.)

On August 22, 2019, Defendant Bally's filed the instant Motion to Bar Plaintiff's Liability Expert and for Summary Judgment. (Doc. No. 71-2.) In its Motion, Defendant argues Colbert's testimony should be barred because: (1) he is not qualified to offer opinions in this matter; (2) his opinions are based upon unreliable methodologies; and (3) his opinions are not relevant for the trier of fact. (See id. at 9-22.) Moreover, Defendant argues it is entitled to summary judgment with respect to the negligence claim because it did not own the disputed area, so it did not owe Plaintiff a duty to clean or remove feces from the area. (See id. at 22-40.) In support it claims: (a) Plaintiff fell on the Boardwalk, which Defendant does not own; and (b) the City of Atlantic City does not require Defendant to clean up or monitor the Boardwalk because it is not considered a public sidewalk. (See id. at 16.)

On August 30, 2019 Plaintiff filed Opposition to Defendant's Motion. (Doc. No. 72.) In her Opposition, Plaintiff argues Colbert is qualified to render his opinion based on his experience, his opinions are reliable because of that experience, and thus his

opinions are fit to assist the trier of fact. (See id. at 219-27.) Moreover, she argues Defendant is not entitled to summary judgment because there is a genuine dispute of material fact over the ownership of the area where Plaintiff slipped and fell and whether it is a public sidewalk. (See id. at 228.)

III. STANDARD OF REVIEW

A. The Daubert Standard on the Admissibility of Expert Witness Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony. See Fed. R. Evid. 702. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Id.

In Daubert v. Merrell Dow Pharmaceuticals, Inc., the United States Supreme Court provided the analytical framework to determine the admissibility of expert testimony under Rule 702. 509 U.S. 579 (1993). Daubert held that Rule 702 imposes a “gatekeeping” obligation on the trial court to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” Id. at 598. Also under Rule 702, the Third Circuit held that it “has three major requirements: (1) the proffered witness must be an expert, *i.e.*, must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.” Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). These requirements are also referred to as “qualification, reliability and fit.” Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003).

i. Qualification

*4 First, the Third Circuit has “interpreted Rule 702’s qualification requirement liberally.” Pineda, 520 F.3d at 244 (citing Schneider, 320 F.3d at 404; In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994)). Accordingly, a “broad range of knowledge, skills, and training qualify an expert.” Paoli, 35 F.3d at 741. Because both the “substantive” and “formal” qualifications of an expert are viewed liberally, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” Id. Thus, “it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate.” Pineda, 520 F.3d at 244 (quoting Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996)).

ii. Reliability

Turning to the “reliability” requirement, the Third Circuit has interpreted reliability “to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” Pineda, 520 F.3d at 244 (internal quotations omitted) (quoting Paoli, 35 F.3d at 742). Notably, “[t]he evidentiary requirement of reliability is lower than

the merits standard of correctness.” *Id.* at 744. Admissibility turns “on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined.” *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). When examining expert testimony that is based on practical experience, rather than academic theories, “the *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable” because the reliability of testimony from a practical experience expert “depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” *States v. Fernwood Hotel and Resort*, No. 12-906, 2014 WL 198568, at *3 (M.D. Pa. Jan. 15, 2014) (quoting *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000)).

iii. Fit

To satisfy the “fit” requirement, “the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Schneider*, 320 F.3d at 404. For expert testimony to meet the *Daubert* “fit” requirement, it must “assist the trier of fact to understand the evidence or to determine a fact in issue.” *Fed. R. Evid.* 702. “This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591 (internal quotations omitted) (citing *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)).

B. The Summary Judgment Standard

Granting summary judgment is an extraordinary remedy. Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” *Fed. R. Civ. P.* 56(a). In reaching this decision, the Court must determine whether “the pleadings, depositions, answers to interrogatories, admissions, and affidavits show there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law.” *Favata v. Seidel*, 511 F. App'x 155, 158 (3d Cir. 2013) (internal quotations omitted) (quoting *Azur v. Chase Bank, USA, Nat'l Ass'n*, 601 F.3d 212, 216 (3d Cir. 2010)). “A disputed issue is “genuine” only if there is sufficient evidentiary basis on which a reasonable jury could find for the non-moving party[.]” *Kaucher v. Cnty. of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). For a fact to be considered “material,” it “must have potential to alter the outcome of the case.” *Favata*, 511 F. App'x at 158. Once the proponent of summary judgment “points to evidence demonstrating no issue of material fact exists, the non-moving party has the duty to set forth specific facts showing that a genuine issue of material fact exists and that a reasonable factfinder could rule in its favor.” *Id.* (quoting *Azur*, 601 F.3d at 216).

*5 In deciding a motion for summary judgment, “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Id.* (alteration in original) (quoting *Chambers ex rel. Chambers v. Sch. Dist. of Phila. Bd. of Educ.*, 587 F.3d 176, 181 (3d Cir. 2009)). The Court's task is not to resolve disputed issues of fact, but to determine whether there exist any factual issues to be tried. See *Anderson*, 477 U.S. at 247-49. Whenever a factual issue arises which cannot be resolved without a credibility determination, at this stage the court must credit the non-moving party's evidence over that presented by the moving party. See *id.* at 255. If there is no factual issue, and only one reasonable conclusion could arise from the record regarding the potential outcome under the governing law, summary judgment must be awarded in favor of the moving party. See *id.* at 250.

IV. ANALYSIS

In the instant Motion, Defendant contends: (1) Colbert's testimony should be barred because it does not meet the qualification, reliability and fit requirements; and (2) it is entitled to summary judgment because it did not owe a duty of care to Plaintiff as she did not slip on its property. (See Doc. No. 71-2 at 9-40.) Conversely, Plaintiff submits Colbert's testimony is admissible and there is a genuine dispute of material fact about whether Plaintiff fell on Defendant's property. (See Doc. No. 72 at 219-28.) Each issue will be discussed seriatim.

A. Defendant's Motion to Bar Plaintiff's Liability Expert Will Be Denied

i. Plaintiff's Expert is Qualified to Render an Opinion on the Hotel and Lodging Industry Customs and Defendant's Duty of Care

Defendant argues that Colbert is not qualified to offer his opinion on the hotel and lodging industry customs and Defendant's duty of care based on his education, training, and experience. (See Doc. No. 71-2 at 13.) Plaintiff, however, submits that under the liberal qualification standard, Colbert is qualified in this case to render his opinion under [Rule 702](#). (See Doc. No. 72 at 220-21.)

The Third Circuit has consistently emphasized a liberal policy of admissibility under [Rule 702](#), which extends to the formal qualification of experts. See [Paoli II](#), 35 F.3d at 741; see also [Pineda](#), 520 F.3d at 243. In addition, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” [Paoli II](#), 35 F.3d at 741. For example, in [Hammond v. International Harvester Co.](#), 691 F.2d 646 (3d Cir. 1982), the Third Circuit found that an automobile and agricultural equipment salesperson who taught high school automobile classes qualified as an expert in a personal injury case involving a tractor. The [Hammond](#) court found that “[p]ractical experience as well as academic training and credentials may be the basis of qualification (as an expert witness).” [Id.](#) at 653 (quoting [Moran v. Ford Motor Co.](#), 476 F.2d 289, 291 (8th Cir. 1973) (internal quotation omitted)); see also [Lauria v. Nat'l R.R. Passenger Corp.](#), 145 F.3d 593, 599 (3d Cir. 1998) (foreman's years of experience with railroad track equipment, maintenance, and safety qualified him to testify as an expert on Amtrak's duty to maintain railroad track). Additionally, in [States v. Fernwood Hotel and Resort](#), a case involving a falling glass pane window, a defendant challenged a purported glass expert's opinion because the expert had not taken engineering courses, was not a licensed engineer, and did not hold himself out as an engineer. See 2014 WL 198568, at *2. The court disagreed, finding the expert qualified based on his thirty-nine years' experience in the glass industry, yearly attendance at conferences to learn about new glass materials, and “extensive personal and practical experience in the glass industry....” [Id.](#)

*6 Similarly, Colbert has extensive practical experience, academic training, and credentials in the hotel and lodging industry. He received a Bachelor of Science in Business Administration from University of Denver's School of Hotel and Restaurant Management. (See Doc. No. 71-3 at 51.) Additionally, he has worked in operations and corporate hotel management for over thirty years and has been certified for over twenty-one years as a Hotel Administrator by the American Hotel & Lodging Association, the highest certification in the hotel and lodging industry. (See Doc. No. 72 at 221.) He also maintains his own consulting business that specializes in operating standards, property control, and premises liability. (See [id.](#))

Given his considerable experience, education, and credentials in the hotel and lodging area, Colbert is qualified to render an opinion in this case on hotel and lodging industry customs and Defendant's duty of care to Plaintiff. Any argument that Colbert's education, experience, or training does not provide a viable industry standard goes to the weight of his testimony, not its admissibility.

ii. The Opinion of Plaintiff's Expert is Based on Reliable Reasoning

Next, Defendant argues Colbert does not use any reliable methodology to support his opinions. (See Doc. No. 71-2 at 4-6.) To the contrary, Plaintiff alleges that Colbert's testimony is reliable because he uses accepted standards and practices learned through his experience, industry publications, and informal resources. (See Doc. No. 72 at 226.)

The Third Circuit has interpreted reliability “to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” [Pineda](#), 520 F.3d at 244 (internal quotations omitted) (quoting [Paoli](#), 35 F.3d at 742). Notably, “[t]he evidentiary requirement of reliability is lower than the merits standard of correctness.” [Id.](#) at 744. Admissibility turns “on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined.” [Kannankeril](#), 128 F.3d at 806.

Defendant urges the Court to rely on a list of factors cited in Daubert, e.g., a testable hypothesis, peer review, publication, potential error rate, and compare those factors to Colbert's report. (See Doc. No. 71-2 at 14.) It is well established, however, that these factors "are neither exhaustive nor applicable in every case." Kannankeril, 128 F.3d at 806-07. The Daubert Court "made clear that its list of factors was meant to be helpful, not definitive." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 151 (1999). And when examining expert testimony that is based on practical experience, rather than academic theories, "the Daubert factors (peer review, publication, potential error rate, etc.) simply are not applicable" because the reliability of testimony from a practical experience expert "depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." Fernwood Hotel and Resort, 2014 WL 198568, at *3 (quoting Hankey, 203 F.3d at 1169).

Here, Colbert renders his opinion based on his knowledge and experience in the hotel and lodging industry. (See Doc. Nos. 71-3 at 51; 72 at 221.) As set forth when discussing his qualifications, he has extensive experience with hotels, gleaned from his career in the industry. (See Doc. No. 72 at 221.) He has over thirty-years of experience working in the hotel and lodging industry and holds a CHA, the highest industry certification. (See id.) His personal experience gives credence to the reliability of his opinion on hotel and lodging industry standards.

Moreover, he bases his opinion upon careful review of the evidence and his understanding of the hotel and lodging industry. (See id. at 224; Doc. No. 71-3 at 43, 45, 54.) In his report and deposition, Colbert cites to the American Hotel and Lodging Association's publication titled Security and Loss Prevention Management for inspections and monitoring standards. (See Doc. No. 72 ¶ 26.) These standards offer that "it is customary and highly important daily practice in the lodging industry to properly and thoroughly inspect the lodging premises for hazards and other potential safety concerns or threats which could cause injuries to individuals on the property." (Doc. No. 71-3 at 45.) He also cites to an article in a publication titled Hotel & Motel Management, which states that the industry standard is for inspections to be conducted "as often as is reasonable in light of frequency and use." (Id.)

*7 In sum, the fact that Colbert does not use a testable theory or methodology subject to peer review does not render his testimony unreliable under Rule 702. To the contrary, his vast experience in the hotel and lodging industry and the publications he references supports the reliability of his opinion.

iii. The Opinion of Plaintiff's Expert is "Fit" to Assist the Trier of Fact

Defendant argues Colbert's opinion is of no use to the trier of fact because of its unreliability. (See Doc. No. 71-2 at 20-22.) Plaintiff submits, however, that Colbert's opinion will assist a trier of fact because his testimony centers on the sufficiency of Bally's safety and inspection procedures, which will assist an average juror in understanding whether hotels owe their patrons a duty to inspect their premises. (See Doc. No. 72 at 226-27.)

To satisfy the "fit" requirement, "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." Schneider, 320 F.3d at 404. For the reasons set forth in the preceding two sections, Colbert's testimony is relevant in determining the hotel and lodging standard of care and what duty, if any, Defendant owed to Plaintiff, and this will assist a jury. Any argument that Colbert is not "fit" to assist the trier of fact goes to the weight of his testimony, not its admissibility.

Therefore, for the foregoing reasons, the Court will deny Defendant's Motion to Bar Plaintiff's Liability Expert.

B. Defendant's Motion for Summary Judgment Will Be Denied Because There Is a Genuine Dispute over Ownership of the Property Where Plaintiff Fell

Next, Defendant moves for summary judgment, arguing that Bally's did not owe Christoforetti a duty of care to keep the premises reasonably safe because: (a) Plaintiff fell on the Boardwalk, which Defendant does not own; and (b) the City of Atlantic City does not require Defendant to clean up or monitor the Boardwalk because it is not considered a public sidewalk. (See Doc. 71-2

at 16.) Plaintiff refutes these arguments, claiming Defendant does own and control the area where she slipped. (See Doc. No. 72 ¶ 12.) When viewing the evidence in the light most favorable to Plaintiff, there is a genuine dispute over who owned the property where Plaintiff slipped and fell. Therefore, summary judgment on Bally's Defendants' direct liability will be denied.

“The fundamental elements of a negligence claim are a duty of care owed by the defendant to the plaintiff, a breach of that duty by the defendant, injury to the plaintiff proximately caused by the breach, and damages.” Robinson v. Vivirito, 86 A.3d 119, 124 (N.J. 2014) (citing Jersey Cent. Power & Light Co. v. Melcar Util. Co., 59 A.3d 561, 571 (N.J. 2013); Weinberg v. Dinger, 524 A.2d 366, 373 (N.J. 1987)). “Determination of the existence of a duty largely depends on weighing the relationship of the parties, the nature of the risk, and the public interest in the proposed solution.” Kelly v. Gwinnell, 476 A.2d 1219, 1222 (N.J. 1984). Whether Defendant owed a duty of care to Plaintiff turns in part on an underlying factual issue over who owns the area where Plaintiff fell. If Bally's owned the area where Christoforetti fell, they owed a duty to keep the premises reasonably safe. If Bally's did not own the area, however, then they did not owe Christoforetti a duty of care.

*8 In support of its argument, Bally's posits that it was not liable for Plaintiff's injuries because she fell on the Boardwalk, which it is not responsible to maintain. (See Doc. No. 71-2 at 16.) Under New Jersey law, Atlantic City is exclusively responsible for maintenance of the Boardwalk. See Horn v. Peanut World Co., 837 F. Supp. 701, 704 (E.D. Pa. 1993). For example, in Horn v. Peanut World Co., plaintiff exited defendant's store that opened directly onto the Boardwalk and tripped on a raised nail protruding from the Boardwalk. See id. at 701. Plaintiff sued defendant for her resulting damages. See id. The court held that the Boardwalk, unlike the sidewalk, was owned by Atlantic City as a public park. See id. at 704. Accordingly, it concluded:

Because the Boardwalk, unlike a sidewalk, is a City-owned public park which Atlantic City tightly controls and strictly regulates, we do not believe that it qualifies as a common sidewalk. The maintenance duties for the Boardwalk are exclusively in the hands of the City. Not only does the City appear conscientiously to maintain the Boardwalk, but given that the abutting store owners are not permitted to place any objects on the Boardwalk, or drive any vehicles there without a permit, it would be difficult, if not impossible, for those owners to perform repairs in the area.

Id.

Here, there is a genuine dispute of material fact as to whether the slip and fall happened on Defendant's property. Defendant relies on Horn, contending that Plaintiff fell on the Boardwalk that Atlantic City is exclusively responsible for controlling and maintaining. (See Doc. No. 71-2 at 16.) However, Plaintiff avers that she did not fall on the Boardwalk, but on Bally's property. (See Doc. No. 72 at 228-30.) In support, she submits tax maps, satellite images, and a tax accessor's opinion that suggest Defendant owned and controlled the area outside the Casino's entrance.³ (See id.) Given this evidence, there is a genuine dispute over whether the area outside the Casino's entrance was the Boardwalk or Defendant's property.

Moreover, this case is distinguishable from Horn. In Horn, there was no dispute that once a patron left the establishment's entrance, he or she stepped onto the Boardwalk. See Horn, 837 F. Supp. at 704. Here, however, because the entrance at issue is on a diagonal angle to the Boardwalk and apparently does not sit flush with it, there is a dispute over whether one steps immediately onto the Boardwalk when entering Defendant's establishment. (See Doc. No. 72 at 228-30.) The ownership dispute here makes Horn inapplicable.

When looking at the evidence in the light most favorable to Plaintiff, there is a genuine dispute of material fact about Defendant's ownership of the area where Plaintiff slipped and fell, and therefore summary judgment will not be granted in favor of Defendant.⁴

V. CONCLUSION

*9 For the foregoing reasons, Defendants Motion to Bar Plaintiff's Liability Expert and For Summary Judgment (Doc. No. 71) will be denied. An appropriate Order follows.

All Citations

Slip Copy, 2021 WL 3879074

Footnotes

- 1 The suffix "CHA" refers to the title of "Certified Hotel Administrator," the highest certification from the American Hotel and Lodging Educational Institute.
- 2 As will be discussed in more detail below, the parties dispute the shape of Defendant's property lot and whether Defendant slipped on the Boardwalk or Bally's property.
- 3 Defendant argues the tax maps, satellite images, and tax accessors opinion should not be considered because they were offered by Plaintiff after the deadline for fact and expert discovery. (See Doc. No. 73 at 8.) However, these items are public information that the Court can take judicial notice of under [Federal Rule of Evidence 201](#).
- 4 For purposes of this Opinion, the Court need not address Defendant's assertion that Atlantic City does not require Defendant to clean up or monitor for feces under any ordinance because the Court must first resolve for summary judgment purposes the underlying dispute over ownership of the property where Plaintiff slipped and fell. Given that summary judgment is being denied, the cleanup requirements of Atlantic City are a matter for trial.

2014 WL 198568

Only the Westlaw citation is currently available.

United States District Court,
M.D. Pennsylvania.

Richard A STATES, Jr., et al., Plaintiffs,

v.

FERNWOOD HOTEL AND RESORT, et al., Defendants.

Civil Action No. 12–0906.

I

Jan. 15, 2014.

Attorneys and Law Firms

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Opinion

JOEL H. SLOMSKY, District Judge.

*1 Before the Court is Defendants' Motion to Exclude the Testimony of Morris Silberman, or in the Alternative, for a Daubert Hearing. (Doc. No. 28.) In deciding this Motion, the Court has reviewed the Motion (Doc. No. 28), Defendants' Brief in Support (Doc. No. 29), Plaintiffs' Response (Doc. No. 33), Plaintiffs' Brief in Opposition (Doc. No. 34), and supporting exhibits submitted by the parties.

By way of background, on June 19, 2010, Plaintiff Richard States, Plaintiff Amaryllis Roman and their daughter B.L.S., a minor, were seated in Defendants' Wintergreens Restaurant. (Doc. No. 3 at 3.) The restaurant was enclosed by a greenhouse-like structure, with double pane glass windows comprising the walls and roof. Suddenly, the bottom pane of a window came falling down from the ceiling and hit Plaintiff Richard States on the head, resulting in *injuries to his head and neck*. (*Id.*) Plaintiffs allege claims of negligence against Defendants. (*Id.*) Plaintiff Roman also alleges claims of negligent infliction of emotional distress and loss of consortium. (*Id.* at 3–9.)

As a preliminary matter, the Court will not hold a *Daubert* hearing on the Motion to Preclude the Testimony of Morris Silberman. The decision “to hold [a *Daubert* hearing] rests in the sound discretion of the district court” and, as noted by the Third Circuit, a *Daubert* hearing is not always required. *Padillas v. Stork–Gamco, Inc.*, 186 F.3d 412, 418 (3d 1999). There is a full record before the Court on this issue including Silberman's expert report and deposition. Under Third Circuit precedent, nothing more is required for a court to determine the admissibility of an expert witness. See *Oddi v. Ford Motor Co.*, 234 F.3d 136, 154 (3d Cir.2000) (Upholding a district court's decision to deny a *Daubert* hearing where the court “already had before it the depositions and affidavits of the plaintiff's experts.”)

The testimony at issue is that of Plaintiffs' expert, Morris Silberman. Silberman has been in the glass business for thirty-nine years. (Doc. No. 33 at 4.) He began as a glazier in the 1970's and has since run companies engaged in glass installation for both homes and offices. (*Id.*) Every year, he attends classes in the glass field to keep current on new materials. (*Id.* at 45.) He oversees and troubleshoots glass installation projects and is familiar with building codes in the tri-state New York area. (*Id.*) He has

worked with tempered glass and with greenhouse structures similar to the structure in Wintergreens Restaurant. (*Id.*) Throughout his career he has trained over 200 apprentice glaziers, and builders rely on him for his glass expertise. (Doc. No. 33 at 35.)

In his report, Silberman found that the Wintergreens Restaurant's glass structure was at least twenty-five years old and had not been properly maintained. He found that the glass was “abused by drilling holes, hanging chains and hooks, a bar attached to the structure, leaking thermo seals, temperature fluctuations and a lack of maintenance,” and that this abuse weakened the structure, causing a glass pane to fall on Plaintiff Richard States. (Doc. No. 33 at 7.) He further found that the structure's abuse “would alert any reasonable restaurant owner to the potential danger to its patrons sitting underneath the glass roof.” (Doc. No. 33 at 7.)

*2 Silberman's findings are based on his review of photographs from the scene of the accident, including photos of the glass structure, the broken pane, the shattered glass, and the structure's window frames. (*Id.* at 5.) Additionally, he reviewed Plaintiffs' depositions, the deposition of Andrew Wolf, a designee for the corporation, and the report of defense expert, Dr. Paul Verghese, Ph.D. He also reviewed Plaintiff States' medical records from the accident. (*Id.*)

Defendants argue that Silberman's testimony is inadmissible under [Federal Rule of Evidence 702](#). Rule 702, which “governs the admissibility of expert testimony, has a liberal policy of admissibility.” *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir.1997). In *Pineda v. Ford Motor Co.*, 520 F.3d 237 (3d Cir.2008), the Third Circuit held that Rule 702 “has three major requirements: (1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.” *Id.* at 244. These requirements are also referred to as “qualification, reliability and fit.” *Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir.2003). For the following reasons, the Court finds that Silberman's testimony satisfies the requirements of Rule 702.

Qualification

First, the Third Circuit has “interpreted Rule 702's qualification requirement liberally.” *Pineda*, 520 F.3d at 244 (citing *Schneider*, 320 F.3d at 404; *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir.1994)). Accordingly, a “broad range of knowledge, skills, and training qualify an expert.” *Paoli*, 35 F.3d at 741. Because both the “substantive” and “formal” qualifications of an expert are viewed liberally, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” *Id.* For example, in *Hammond v. International Harvester Co.*, 691 F.2d 646 (3d Cir.1982), the Third Circuit found that an automobile and agricultural equipment salesperson who taught high school automobile classes qualified as an expert in a personal injury case involving a tractor. The *Hammond* Court found that “[p]ractical experience as well as academic training and credentials may be the basis of qualification (as an expert witness).” *Id.* at 653 (quoting *Moran v. Ford Motor Co.*, 476 F.2d 289, 291 (8th Cir.1973) (internal quotation omitted); see also, *Lauria v. Nat'l R.R. Passenger Corp.*, 145 F.3d 593, 599 (3d Cir.1998) (Foreman's years of experience with railroad track equipment, maintenance, and safety qualified him to testify as an expert on Amtrak's duty to maintain railroad track.)

Defendants argue that Silberman is not qualified to testify as an expert because he “does not claim to have taken any engineering courses, is not a licensed professional engineer and does not hold himself out as an engineering expert in any specialized field of engineering.” (Doc. No. 29 at 10.) As previously mentioned, Silberman has been in the glass business for thirty-nine years. Builders rely on his expert opinion, and have done so for years. Every year, he attends classes in the glass field to keep current on new materials. In this case, Silberman's extensive personal and practical experience in the glass industry qualifies him an expert. As such, he more than satisfies Rule 702's liberal “qualification” requirement.

Reliability

*3 Turning to the “reliability” requirement, the Third Circuit has interpreted reliability “to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” *Pineda*, 520 F.3d at 244 (quoting *Paoli*, 35 F.3d at 742) (internal quotations omitted). Notably, “[t]he evidentiary requirement of reliability is lower than the merits standard of correctness.” *Id.* at 744. Admissibility turns “on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined.” *Kannankeril*, 128 F.3d at 806.

Defendants urge the Court to rely on a list of factors cited in *Daubert* and the Third Circuit case *United States v. Downing*, and to compare the factors to the ones relied on by Silberman in his methodology. The factors Defendants argue that the Court must consider are: “(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–94, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); *United States v. Downing*, 753 F.2d 1224, 1238–39 (3d Cir.1985).

It is well established, however, that these factors “are neither exhaustive nor applicable in every case.” *Kannankeril*, 128 F.3d at 806–07. The *Daubert* Court “made clear that its list of factors was meant to be helpful, not definitive.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). Indeed, some courts have held that when examining expert testimony that is based on practical experience, rather than academic theories, “the *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable,” because the reliability of testimony from a practical experience expert “depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir.2000).

Silberman rendered his opinion after a careful review of the evidence. It is not based on a scientific hypothesis that can be published or peer reviewed. His opinion is supported, though, not by a testable theory, but by his understanding of glass products. Silberman has extensive experience with tempered glass, gleaned from his career in the industry, installing glass, especially in greenhouse structures similar to the one from which the glass fell on Plaintiff States, and serving as a glass consultant on major projects. His thirty-nine years of personal and practical experience support the reliability of his opinion. As such, many of the factors Defendants ask the Court to examine—peer review, publication, potential rate of error, general acceptance, standards controlling the technique's operation, and the relationship of the technique to reliable methods—do not apply to Silberman's testimony.

*4 Because his opinion is based solely on his experience, however, the Court has examined Silberman's qualifications and the non-judicial uses to which his opinions have been put. *Downing*, 753 F.2d at 1239. As discussed, Silberman has experience in the glass field in both the private and commercial context. What most impresses the Court is his experience with tempered glass, the kind of glass at issue in this case, and his experience with greenhouse-like structures, the type of structure at issue in this case. His years of experience and relevant expertise provide the necessary support for his opinions. Also, his opinions have been requested in a non-judicial context, as he has been brought on as a consultant for glasswork in both homes and offices.

Silberman's testimony is similar to the expert testimony presented in *Pineda*. In that case, the Third Circuit allowed testimony from an engineer who worked extensively in the glass and ceramics fields. The expert testified that an automobile manufacturer should have included in its service manual a step-by-step guide on how to prevent the failure of glass in a car's rear liftgate. 520 F.3d at 245. Defendant questioned the admissibility of the expert's testimony, arguing that his opinion was based on nothing more than his “generalized experience.” *Id.* at 248. However, the Third Circuit recognized that the expert's opinion was supported by his years of experience in the glass field and that he was not required to test his opinion. The Court found that:

[Plaintiff] proffered [the expert] as an engineering expert who understood the stresses and forces that might cause glass to fail. [The expert's] specialized, rather than generalized, experience in this area allowed him to recognize that exerting a force on one area of the rear liftgate glass before exerting a force on another area of the glass could lead to its shattering. [The expert] did not have to develop or test alternative warnings to render an opinion that the ... service manual did not provide adequate, step-by-step instructions to account for the different stresses that might be exerted when an automobile technician

replaces the rear liftgate brackets and hinges, or that the lack of instructions was a safety issue for the technician.

Id. Similarly, Silberman's opinion as to the structural integrity of the Wintergreens Restaurant's glass enclosure is based on his years of specialized, rather than generalized, experience in the glass field. His review of photographs of the area of the greenhouse where the glass fell and other items led him to conclude that several “holes, hanging chains and hooks, a bar attached to the structure, leaking thermo seals, temperature fluctuations and a lack of maintenance” caused the structure to weaken and the glass to fall. (Doc. No. 33 at 7.) His opinion therefore is supported by his experience, and meets Rule 702's reliability requirement.

Fit

Finally, Silberman's testimony also “fits” the issues in this case. In order to satisfy the “fit” requirement, “the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Schneider*, 320 F.3d at 404. Because this case turns on what caused the glass pane to fall onto Plaintiff Richard States, Silberman's opinion that the glass fell because of years of neglect and abuse certainly would assist the trier of fact and is relevant for the purposes of the case.

Conclusion

*5 For the foregoing reasons, Silberman will be permitted to testify at trial. “Any dispute ... about the strength of [Silberman's testimony] in this case should be resolved by the jury.” *Pineda*, 520 F.3d at 249. Defendants' Motion to Exclude the Testimony of Morris Silberman, or in the Alternative, for a *Daubert* Hearing (Doc. No. 28) will be denied.

ORDER

AND NOW, this 15th day of January 2014, upon consideration of Defendants' Motion to Exclude the Testimony of Morris Silberman, or in the Alternative, for a *Daubert* Hearing (Doc. No. 28), Defendants' Brief in Support (Doc. No. 29), Plaintiffs' Response (Doc. No. 33), Plaintiffs' Brief in Opposition (Doc. No. 34) and supporting exhibits submitted by the parties, it is **ORDERED** that Defendants' Motion to Exclude the Testimony of Morris Silberman, or in the Alternative, for a *Daubert* Hearing (Doc. No. 28) is **DENIED**.

All Citations

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1. [*Wisconsin v. Indivior Inc. \(In re Suboxone \(Buprenorphine Hydrochloride & Naloxone\) Antitrust Litig.\), 2020 U.S. Dist. LEXIS 219949*](#)

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Wisconsin v. Indivior Inc. (In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.)

United States District Court for the Eastern District of Pennsylvania

November 24, 2020, Decided; November 24, 2020, Filed

MDL NO. 2445 13-MD-2445; CIV. A. NO. 16-5073

Reporter

2020 U.S. Dist. LEXIS 219949 *; 2020 WL 6887885

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION THIS DOCUMENT RELATES TO, Wisconsin, et al. v. Indivior Inc. et al. Case No. 16-cv-5073 STATE OF WISCONSIN By Attorney General Brad D. Schimel, et al., Plaintiffs, v. INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al., Defendants.

Prior History: [*Wisconsin v. Indivior Inc. \(In re Suboxone \(Buprenorphine Hydrochloride & Naloxone\) Antitrust Litig.\)*](#), 2017 U.S. Dist. **LEXIS** 145501, 2017 WL 3967911 (E.D. Pa., Sept. 8, 2017)

Core Terms

tablets, film, generic, reliability, opines, patients, studies, regulations, substitution, manufacturers, expert testimony, methodology, products, therapeutic, surveys, misleading, marketing, cross-examination, prescriptions, website, negotiations, prescribing, Omnibus, qualifications, statistical, documents, advertising, exposure, pharmaceutical, pediatric

Counsel: [*1] SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION, IN RE (2:13-md-02445): JAMES R. DUGAN , II, THE DUGAN LAW FIRM, NEW ORLEANS, LA.

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For INDIVIOR INC., formerly known as, RECKITT BENCKISER PHARMACEUTICALS, INC., Defendant (2:16-cv-05073): DANIEL D. DEVOUGAS, JONATHAN BERMAN, JONES DAY, WASHINGTON, DC; NICOLAS A. HIDALGO, JONES DAY, CHICAGO, IL; TIFFANY D. LIPSCOMB-JACKSON, JONES DAY, COLUMBUS, OH.

For [*13] AQUESTIVE THERAPEUTICS, INC., formerly known as, MONOSOL RX, LLC, Defendant (2:16-cv-05073): ALEXANDER BILUS, LEAD ATTORNEY, SAUL EWING ARNSTEIN & LEHR LLP, CENTER SQUARE WEST, PHILADELPHIA, PA; DANIEL ALDRICH, JAMES F. HIBEY, JESSICA I. ROTHSCHILD, LEAD ATTORNEYS, STEPTOE & JOHNSON LLP, WASHINGTON, DC; JAMIE LUCIA, LEAD ATTORNEY, STEPTOE & JOHNSON LLP, Spear Tower, SAN FRANCISCO, CA.

For DIRECT PURCHASER PLAINTIFFS, Amicus (2:16-cv-05073): RICHARD D. SCHWARTZ, BERGER MONTAGUE PC, PHILADELPHIA, PA.

Judges: MITCHELL S. GOLDBERG, J.

Opinion by: MITCHELL S. GOLDBERG

Opinion

Goldberg, J.

MEMORANDUM

Defendant Reckitt Benckiser, Inc. ("Defendant") manufactures Suboxone, a drug commonly used to combat opioid addiction.¹ Suboxone previously came in tablet form, but in 2010, citing safety concerns, Defendant effectuated a change in the administration of this drug, switching from tablet to sublingual film. Various purchasers/consumers of Suboxone claimed that this switch was anticompetitive and solely designed to maintain Defendant's market exclusivity—a scheme known as a "product hop." These claims have resulted in multi-district, antitrust litigation before this Court.

As discovery and class certification litigation have come [*14] to a close, the parties have raised numerous challenges under [Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 \(1993\)](#), seeking exclusion of all or selected portions of nine expert witnesses anticipated opinions. This Opinion explains my reasoning for the resolution of these motions and will hopefully set forth a clearer path towards trial.

I. FACTUAL AND PROCEDURAL BACKGROUND²

The Plaintiffs in this multi-district litigation case allege anticompetitive conduct by Defendant Reckitt Benckiser, Inc. in connection with their Suboxone product. Plaintiffs' claims focus on a relatively new theory of antitrust liability, referred to as a "product hop," pursuant to the unique regulatory and statutory scheme that governs the marketing and distribution of pharmaceutical drugs. Under this theory, a pharmaceutical company makes modest reformulations to a brand-name drug prior to the expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

The Plaintiffs are comprised of a class of Direct Purchasers of Suboxone ("Direct Purchasers" or "DPPs"), a class of End Payors of Suboxone ("End Payors" or "EPPs"), and a group of States' Attorneys General (the "States") (collectively, "Plaintiffs"). These [*15] Plaintiffs claim that Defendant switched from a Suboxone tablet to a sublingual Suboxone film for the purpose of foreclosing generic competition. According to Plaintiffs, this switch (the "product hop") was accompanied by Defendant disparaging the tablet through fabricated safety concerns and ultimately removing Suboxone tablets from the market just as generic Suboxone tablets were able to begin competing. Defendant is also accused of having manipulated FDA regulations to delay the entry of generic Suboxone onto the market through the filing of an unsubstantiated Citizen Petition and of "misconduct" during the shared Risk Evaluation and Mitigation Strategies ("REMS") process. According to Plaintiffs, Defendant's conduct foreclosed competition, thereby allowing Defendant to unlawfully maintain a monopoly in violation of [Section 2 of the Sherman Act](#) and overcharge for its Suboxone products. Defendant readily acknowledges the product switch, but strenuously responds that the switch was done for the pro-competitive purpose of marketing and selling an improved, safer, and superior product.

During the pendency of Defendant's appeal of the class certification ruling to the Third Circuit, I directed [*16] the parties to file any Daubert motions that would not be impacted by the Third Circuit's certification decision. The parties have filed the following motions: (1) the DPPs' Motion to Exclude Certain Opinions of Defendant's Experts Nicholas M. Fleischer and Sheldon T. Bradshaw; (2) the States' Motion to Exclude the Testimony of Defendant's Expert Dolores Curtis, Ph.D.; (3) Defendant's Omnibus Motion to Exclude Certain of the Opinions of Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot; and (4) Defendant's Motion to Exclude Plaintiffs' Expert Opinions Asserting or Relying upon Assertions that Alleged Reckitt Safety Messages Were "False," "Misleading," "Disparaging," "Fabricated," "Fraudulent," "Sham," or "Deceptive."

¹ Reckitt is currently known as Indivior, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. Although Indivior is technically the named defendant in this case, the pleadings and many of the relevant exhibits use the name "Reckitt."

² Rather than re-hashing the complicated regulatory background and factual basis of this case, I incorporate by reference the history set forth in my prior decision certifying a class for both the DPPs and EPPs. [In re Suboxone, 421 F. Supp. 3d 12 \(E.D. Pa. 2019\)](#), aff'd, [967 F.3d 264 \(3d Cir. 2020\)](#). To the extent necessary, I will discuss facts that are pertinent to each particular expert at issue.

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the [*17] product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case

Fed. R. Evid. 702. Rule 702 places district courts in the role of "gatekeeper," requiring courts to "ensure that any and all [expert] testimony . . . is not only relevant, but reliable." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999) (quoting Daubert, 509 U.S. at 589). The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert's qualifications and opinions comply with Federal Rule of Evidence 702. See Daubert, 509 U.S. at 592-93 (citation omitted). Rule 702 has "a liberal policy of admissibility," Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008) (quotation omitted), and "the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702, Advisory Comm Notes (2000). As the Court in Daubert stated: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 595.

The Daubert inquiry "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted).

A. Qualification

In Waldorf v. Shuta, 142 F.3d 601 (3d Cir. 1998), the United States Court of Appeals for the Third Circuit articulated the "qualification" standard for an expert:

Rule 702 requires the witness to have "specialized [*18] knowledge" regarding the area of testimony. The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." . . . We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony "extends to the substantive as well as the formal qualification of experts." . . . However, "at a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman"

Id. at 625 (citations omitted).

Construing this standard, the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). In other words, "an expert's qualifications should be assessed 'liberally,' recognizing that 'a broad range of knowledge, skills, and training qualify an expert as such.'" Thomas v. CMI Terex Corp., No. 07-3597, 2009 U.S. Dist. LEXIS 86623, 2009 WL 3068242, at *5 (D.N.J. Sept. 21, 2009) (quoting Paoli, 35 F.3d at 741). An expert will not be excluded "simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996). The focus, instead, is on whether the qualifications that an expert [*19] does have provide a foundation for the witness to testify meaningfully on a given matter. See Buzzard v. Flagship Carwash of Port St. Lucie, Inc., 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009).

B. Reliability

The reliability restriction requires that the testimony be based upon "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" and that the expert have "good grounds' for his or her belief." [*Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 \(3d Cir. 2003\)*](#) (quotations omitted). In that respect, reliability mandates an examination into the expert's conclusions in order to determine "whether [the conclusions] could reliably flow from the facts known to the expert and [the] methodology used." [*In re Diet Drugs \(Phentermine/Fenfluramine/Dexfenfluramine\) Prod. Liab. Litig., 706 F.3d 217, 225 n.7 \(3d Cir. 2013\)*](#) (quoting [*Oddi v. Ford Motor Co., 234 F.3d 136, 146 \(3d Cir. 2000\)*](#) (internal quotation marks omitted)).

The Third Circuit has identified the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of [*20] the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. [*Elcock v. Kmart Corp., 233 F.3d 734, 745-46 \(3d Cir. 2000\)*](#). Although this list of factors is lengthy, not each factor will be relevant to every reliability analysis. The "test of reliability is 'flexible.'" [*Kumho, 526 U.S. at 141*](#). According to the Supreme Court, "Daubert's list of specific factors neither necessarily nor exclusively applies to all experts." [*Id.*](#) The relevance of the Daubert factors depends "on the nature of the issue, the expert's particular expertise, and the subject of his testimony." [*Id. at 150*](#) (internal quotation marks and citations omitted).

Importantly, the rule does not require the party proffering the expert to demonstrate the "correctness" of the expert's opinion. [*Paoli, 35 F.3d at 744*](#) (concluding that the "evidentiary requirement of reliability" amounts to a lower burden "than the merits standard of correctness"). Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion bears adequate indicia of reliability. [*Id.*](#) Indeed, "[a] judge will often think that an expert has good grounds to hold the opinion . . . even though the judge thinks the opinion otherwise incorrect." [*Id.*](#) Therefore, "[t]he focus . . . must [*21] be solely on principles and methodology, not on the conclusions that they generate." [*Daubert, 509 U.S. at 595*](#). "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." [*i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 852 \(Fed. Cir. 2010\)*](#), [*aff'd, 564 U.S. 91, 131 S. Ct. 2238, 180 L. Ed. 2d 131 \(2011\)*](#).

C. Fit

The issue of fit "is one of relevance and expert evidence which does not relate to an issue in the case is not helpful." [*In re TMI Litig., 193 F.3d 613, 670 \(3d Cir. 1999\)*](#). The standard for fitness is "not that high" but is "higher than bare relevance." [*Paoli, 35 F.3d at 745*](#). To determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." [*Fed. R. Evid. 702\(a\)*](#); see also [*UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 \(3d Cir. 2020\)*](#). "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." [*Id.*](#) (quoting [*Daubert, 509 U.S. at 591*](#)). "Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*." [*Id.*](#) (quoting [*Paoli, 35 F.3d at 743*](#) (emphasis in original)).

III. THE DIRECT PURCHASER [*22] PLAINTIFFS' OMNIBUS DAUBERT MOTION

I first consider the DPPs' Daubert motion to preclude certain opinions by two of Defendant's experts, Nicholas Fleischer and Sheldon Bradshaw.

A. Opinions of Nicholas Fleischer

The DPPs' first challenge involves Dr. Nicholas Fleischer. In order to understand Dr. Fleischer's opinions, some context is necessary.

Plaintiffs' antitrust case theorizes, in part, that, absent Defendant's delay during the shared REMS process,³ generic tablet manufacturers Amneal and Actavis would have brought their generic product to market sooner. In support of that theory, the DPPs offer expert Deborah Jaskot, who concludes that there were no FDA regulatory obstacles to the approval of Amneal and Actavis' ANDAs, and that Defendant's conduct in the REMS process created the sole obstacle and delay in Amneal and Actavis' ability to bring their generic product to market. In response, Dr. Fleischer opines on "regulatory issues involved with the review and approval of Amneal's ANDA 203136 [and] Actavis ANDA 91422." (Decl. of Dan Chiorean ("Chiorean Decl."), Ex.1 ("Fleischer Rep.") ¶ 2.) Dr. Fleischer's opinions will also establish that both ANDAs had multiple deficiencies that delayed [*23] their approval.

The DPPs now seek to exclude Dr. Fleischer's opinions on two subject areas, which I discuss separately.

1. Opinion Testimony Regarding FDA Form 483

One of the key issues in this case concerns whether Defendant's conduct during the shared REMS process resulted in a delay in the approval of the Abbreviated New Drug Applications ("ANDAs") for generic Suboxone. The DPPs' regulatory expert, Deborah Jaskot, opined that if the generics' REMS "were approved by FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame." (Def.'s Opp'n DPPs' Mot., Ex. 5, Report of Deborah Jaskot ("Jaskot Rep.") ¶ 18.) Deborah Jaskot also noted that the FDA, in May 2012, had inspected the MacFarlan Smith facility—the source of Actavis' active pharmaceutical ingredient—and did not find any compliance issues or issue any FDA Form 483s, which would have indicated [Food, Drug and Cosmetic Act](#) problems.⁴ (Def.'s Opp'n DPPs' Mot., Ex. 6, Jaskot Rebuttal Rep. ¶ 62.)

In Dr. Fleischer's responsive report, he concluded, based on an FDA internal progress log, that "Actavis' compliance [*24] deficiencies were separate from the pending REMS issues and Actavis' ANDA could not have been approved prior to their resolution on November 29, 2012." (Fleischer Rep. ¶ 130.) To rebut Ms. Jaskot's assertion about MacFarlan Smith facility, Dr. Fleischer reviewed the FDA's records regarding the May 2012 inspection and discovered that the FDA had, in fact, issued an FDA Form 483. In paragraph four of Dr. Fleischer's June 5, 2019 Supplemental Report, he stated that he "consulted with [his] Current Good Manufacturing Practice ("cGMP") associates at The Weinberg Group [Nita U. Patel and John T. LoPiccolo] who provided [an analysis] of the observations [in Form FDA 483]." (Chiorean Decl., Ex. 3, Fleischer Suppl. To Sur-Rebuttal Report ¶ 4 & n.4.) According to that Report, Dr. Fleischer concluded that the Macfarlan Smith facility faced "a combination of

³As explained in the class certification decision, REMS is a Risk Evaluation and Mitigation Strategy to "manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks. <https://www.btodrems.com/SitePages/Welcome.aspx>. The FDA can also require that generic sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a Single Shared REMS program ("SSRS"), which is a single REMS program to be used by both the sellers of the brand drug and AB-rated generic equivalents.

⁴"An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the [Food, Drug and Cosmetic \(FD&C\) Act](#) and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health." [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form%20483,FD%26C\)%20Act%20and%20related%20Acts](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form%20483,FD%26C)%20Act%20and%20related%20Acts).

unverified analytical validation, untrained analysts, with potential micro contaminant issue leading to potential safety risks" that could have caused a delay in the approval of Actavis' ANDA. (Id. ¶ 4.) Dr. Fleischer opined that "Actavis' compliance deficiencies [at that facility] prevented the FDA from approving its ANDA prior to November [*25] 2012." (Fleischer Sur-Rebuttal Rep. ¶ 24.)

The DPPs contend that this opinion is inadmissible under Daubert because Dr. Fleischer simply took the opinions of two individuals not designated as experts and put them into his own words to "make it flow better." (Chiorean Decl., Ex. 7, Jan. 7, 2020 Dep. of Nicholas Fleischer ("Fleischer Jan. 7, 2020 Dep.") 32:4-12; 121:21-122:13.) According to the DPPs, for each of the "observations" made about deficiencies at the Macfarlan Smith facility, Dr. Fleischer merely adopted the analysis provided to him by Mr. LoPiccolo and Dr. Patel and "transcribed it as the way to get the message across about the seriousness of the observation." (Id. at 122:18-123:6.) The DPPs point out that Dr. Fleischer did not know what methodology Mr. LoPiccolo and Dr. Patel employed in reaching their opinions. (Id. at 34:19-22.) The DPPs further contend that neither Mr. LoPiccolo nor Dr. Patel submitted reports, and their opinions were rendered outside the discovery period, depriving the DPPs of the ability to test the veracity, reliability, education, experience, methodology, or process of these individuals.

The DPPs are correct that "an expert cannot simply be the mouthpiece [*26] of another expert." St. Paul Fire & Marine Ins. Co. v. Nolen Grp., Inc., No. 02-8601, 2005 U.S. Dist. LEXIS 9303, 2005 WL 1168380, at *10 (E.D. Pa. May 13, 2005); see also In re: James Wilson Assocs., 965 F.2d 160, 173 (7th Cir.1992) ("[T]he judge must make sure that the expert isn't being used as a vehicle for circumventing the rule against hearsay.") Nonetheless, "[w]hile experts may not simply 'parrot' ideas of other experts," they "are permitted to rely on materials used by other experts in developing their own opinions." I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants, No. 03-4932, 2008 U.S. Dist. LEXIS 43435, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008) (quotations omitted). Experts "may use a mix of objective data and subjective analysis from another expert to . . . create an admissible report," and the testifying expert's knowledge regarding the underlying facts "go[es] to the weight accorded to [that expert's] report and testimony, rather than its admissibility." Id. (quoting In re Wagner, No. 06-1026, 2007 U.S. Dist. LEXIS 22769, 2007 WL 966010, at *4 (E.D. Pa. Mar. 29, 2007)). Indeed, under Federal Rule of Evidence 703, "an expert may rely on any facts or data 'of a type reasonably relied upon by experts in the particular field in forming opinions,'" even if those underlying facts or data are themselves inadmissible. St. Paul Fire & Marine, 2005 U.S. Dist. LEXIS 9303, 2005 WL 1168380, at *9 (quoting Fed. R. Evid. 703). "Cases have recognized that an expert may rely on the work of others, but the expert must be able to testify to the veracity of that work." Id.; see also CarnegieMellon Univ. v. Marvell Tech. Grp., Ltd., 286 F.R.D. 266, 271 (W.D. Pa. 2012) ("[I]t is well settled that one expert may rely upon another expert's opinion in formulating his own.").

In light of the above precedent, and after review [*27] of the pertinent expert reports, I conclude that Dr. Fleischer's opinions—which are based in part on information received from others—are admissible. I disagree with the DPPs that Dr. Fleischer acted as a "mouthpiece" for his colleagues' opinions. Dr. Fleischer was presented with Ms. Jaskot's rebuttal report and was asked to provide responses to specific issues outlined in that report. (Fleischer Jan. 7, 2020 Dep. 20:1-14.) Dr. Fleischer was also asked to review the FDA Form 483 that showed problems during the inspection of the Macfarlan Smith facility. (Id. at 21:10-16.) Repeatedly, he testified that he made his own observations and formed his own opinions about what that FDA Form 482 demonstrated, and turned to his colleagues solely for consultation and confirmation of opinions he independently formed:

- "I consulted with [Patel and LoPiccolo] only from the purpose of asking them to confirm my observations and my opinions about my review of the 482, to see if they would concur that my opinions and evaluations was similar to what they would have opined in seeing the 483." (Id. at 23:2-8.)
- "When I received that 483 and reviewed it, I found it to be a serious list of observations. And [*28] I sent the 483 to Dr. Patel and Mr. LoPiccolo and said—basically, I told them, I said, I think these are serious, but I would like your confirmation as to if you concur with my opinion that these are serious observations." (Id. at 25:13-20.)
- "I read the 483. I had an opinion that these were serious-enough findings that could impact the FDA making a determination whether a facility was in compliance or not. And that is why I went to Dr. Patel and Mr. LoPiccolo, to confirm my observations that they would agree that they were of a serious nature." (Id. at 28:13-21.)

- "As I said, I'm not repeating, I'm taking [Patel and LoPiccolo's] opinions and editing them into my words. . . . [The Supplemental Sur-Rebuttal Report is] not a conduit of [Patel's and LoPiccolo's] opinions. It is a—taking their opinions and putting them into the words that I wanted to state based on my analysis of those observations." (*Id.* at 32:1-12.)
- "I did not supervise [Patel and LoPiccolo]. I just sent them the 483 and asked them basically, what I've been saying all along, 'do you concur with my opinion that these are serious observations.' . . . [T]heir main responsibility at the Weinberg Group is dealing with GMP-type [*29] issues, almost on a day-to-day basis, which I don't do on a day-to-day basis. So for that reason I said, you know, in order to confirm my opinion, I should ask them to see if they draw the same conclusions as I did." (*Id.* at 33:2-17.)
- "I did not even mention to [Patel and LoPiccolo] what the case was or what drugs they were. I just asked them—as I stated several times before, I had said, 'do you interpret these observations the same way I do that these are serious observations,' without specificity as to what drugs were involved." (*Id.* 45:1-8.)

Dr. Fleischer's reliance on his colleagues to confirm his already-formulated conclusion does not constitute a basis for exclusion. "[A]n expert may expand his or her knowledge by consulting colleagues and journal articles. To hold otherwise would be to require scientists to develop all of their knowledge through their own clinical work or experiments. This is an unrealistic expectation and it ignores the reality of science as a collaborative process." [*Ade/ v. Greensprings of Vermont, Inc.*, 363 F. Supp. 2d 683, 692 \(D. Vt. 2005\)](#). "It would be strange, indeed, if the mere fact that an expert consulted with a similarly qualified colleague to test her theories rendered her conclusions less reliable. That [the expert] does [*30] not have a record of the exact changes [her colleague] proposed (and which were adopted) does not make her method unreliable, although it is a perfectly legitimate ground for cross-examination." [*Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 U.S. Dist. LEXIS 47710, 2011 WL 1673805, at *6 \(E.D. Pa. May 4, 2011\)](#).

The record also reflects that Dr. Fleischer meets the liberal standard for qualification to render these opinions. He testified that cGMPs are "something that [he] encounter[s] in [his] work in helping clients with issues regarding observational findings, 483s and GMP-type issues." (Fleischer Jan. 7, 2020 Dep. 24:8-15.) He further stated, "I even published a paper on CGMPs, so I'm very familiar with CGMPs." (*Id.* at 128:17-19.) He has "read a lot of papers and have read guidances" to give him "an overall familiarity with what CGMPs are." (*Id.* at 129:2-4.) Thus, standing alone, Dr. Fleischer's opinion on the meaning of a cGMP and FDA Form 483 is admissible.⁵ Although Dr. Patel and Mr. LoPiccolo may have a greater expertise on that subject, that fact does not render Dr. Fleischer's independent opinion subject to exclusion. See [*Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 \(3d Cir. 2008\)](#). ("[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed [*31] expert does not have the specialization that the court considers most appropriate." (quotations omitted)). Indeed, the fact that Dr. Fleischer confirmed that opinion with two qualified colleagues could bolster its reliability. To the extent the DPPs believe that Dr. Fleischer has no independent knowledge to support his opinions, that can be the subject of cross-examination and will go to the weight, not the admissibility of his expert report.

2. Testimony About the "Go Live Requirement" For the Generic ANDAs

⁵ Dr. Fleischer's qualifications render this case distinguishable from the Tenth Circuit case of [*TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722 \(10th Cir. 1993\)](#) on which the DPPs rely. In that case, the court found that an expert opinion was inadmissible where the expert "failed to demonstrate any basis for concluding that another individual's opinion on a subjective financial prediction was reliable, other than the fact that it was the opinion of someone he believed to be an expert who had a financial interest in making an accurate prediction." *Id.* at 732.

Unlike [*TK-& Corp.*](#), Dr. Fleischer is qualified and has indicated that he independently reached his opinion. He merely confirmed and corroborated that opinion with Dr. Patel and Mr. LoPiccolo.

The DPPs' also challenge Dr. Fleischer's opinion on the "Go-Live" requirement for generic ANDAs. As set forth above, Plaintiffs' expert, Deborah Jaskot, opined that if the generics' REMS "were approved by FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame." (Jaskot Rep. ¶ 18.) In rebuttal, Dr. Fleischer opined that the BTOD [Buprenorphine-containing Transmucosal product for Opioid Dependence] REMS required a website and call center that could "Go-Live"—i.e., be operational or functioning—prior to the launch of the ANDAs. However, according to Dr. Fleischer neither the website nor the call center were operational until March 5, 2013. (Fleischer Rep. ¶ 93.) He went on to explain:

94. The BPMG [Buprenorphine Products Manufacturers Group] contracted with PPD [an outside vendor] to develop the website and call center components of the REMS program. It took considerable time for the BPMG to select PPD as its "go-live" vendor. And, it took several months (from July 2012 to late December 2012) to finalize the PPD-BPMG agreement regarding the development, operation, and management of the BTOD REMS. . . .

95. The PPD-BPMG agreement anticipated that the launch of the BTOD REMS "go-live" website and call center would occur roughly one to two months after FDA's approval of the BTOD REMS. . . .

96. "In February 2013, the BPMG members requested that PPD expedite the timelines for launch of the call center and website 'to occur on March 1 or as soon as the PPD develops and receives approval of material from the BPMG.'" (Affidavit of Robin Kinard ¶ 34 (quoting PPD000001718).) The BPMG and PPD eventually implemented changes so that the website and call center could be operational on March 5, 2013. . . .

97. Robin Kinard, PPD's Senior Oversight Lead for the BTOD REMS project, even admits that "[g]iven the timing of FDA's final approval on February 22, 2013, PPD and the generic manufacturers could not realistically have completed all tasks necessary for the program's operational launch substantially sooner than the actual 'go-live' date of March 5, 2013." (Affidavit of Robin Kinard ¶ 19.)

98. Regardless of the approval of the REMS, the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date. The original agreement between PPD and the BPMG also anticipated an even later "go-live" date. And importantly, the website and call center issues were not related to any other ANDA deficiency and delayed the launch date of Amneal's product independently of the other deficiencies.

(Fleischer Rep. ¶¶ 94-98.)

The DPPs claim that Dr. Fleischer is unqualified to offer an opinion on this issue. They assert that Dr. Fleischer applied no regulatory expertise, experience, analysis, or methodology, and that he admitted to possessing no education or experience in the areas of website and call center design or launch. The DPPs also contend [*34] that Dr. Fleischer's opinion is directly contradicted by Robin Kinard, the Senior Director of Risk Management at PPD, who is in charge of the website and call center launch and explained that some of the necessary "go-live" work was dependent on first getting REMS approval from the FDA.

According to Defendant, however, unrefuted evidence established that the FDA required a fully operational website and call center before any generic tablet was put into interstate commerce. (Def.'s Opp'n, Exs. 10, 11, 17.) Defendant asserts that Dr. Fleischer, who has almost forty years of experience in the drug approval realm, is qualified to provide the logical opinion that when the FDA conditions a company's product launch on a "fully operational" REMS (including a website) and call center, generic manufacturers cannot sell their products until these elements were operational. Such an opinion, according to Defendant, does not require or even relate to expertise in website and call center design or launch, as suggested by the DPPs.

I agree with Defendant and find Dr. Fleischer qualified to render this opinion on the "Go-live" requirement. Daubert's focus is on whether an expert's qualifications provide [*35] a foundation for the witness to testify meaningfully on a given matter. Dr. Fleischer holds a Ph.D. in Pharmacology. (Fleischer Rep. ¶ 4.) His work "focuses on advising both brand and generic drug companies on the Food and Drug Administration's ('FDA') regulatory process for the approval of innovator and generic drugs, including scientific and regulatory issues relating to the submission and review of applications to the FDA, including new drug applications ('NDA(s)') and abbreviated new drug applications ('ANDA(s)')." (*Id.* ¶ 5.) He has advised clients on regulatory issues relating to the submission and review of at least

400 NDAs and ANDAs. (*Id.* ¶ 6.) Dr. Fleischer also worked at the FDA for seventeen years, most recently as the Director of the Division of Bioequivalence, Office of Generic Drugs. (*Id.* ¶ 8.) He has "wide-ranging experience with FDA regulations, policies, and guidelines" as well as "experience with the specific procedures for filing, amending, and supplementing ANDAs filed under 21 U.S.C. § 355(j) and related statutes." (*Id.* ¶ 14.)

Such extensive experience with the FDA regulatory process for both generic and brand drugs renders him sufficiently qualified to opine that the generics' failure **[*36]** to have a live and running website and call center prior to March 5, 2013 would have, under the FDA's regulations, precluded the generics from launching their products prior to that date. See generally *In re Flonase Antitrust Litig.*, 907 F. Supp. 2d 637, 642 (E.D. Pa. 2012) (finding that expert's "lifelong experience in the field of food and drug regulation demonstrates that he is well-equipped to discuss the FDA's processes for responding to citizen petitions, and that he is qualified to opine on whether a sophisticated petitioner like GSK could have reasonably expected to succeed in changing FDA policy with its petitions."). Such an opinion does not require, as the DPPs contend, any expertise in website or call center design and launch. Indeed, Dr. Fleischer does not attempt to discuss what was required for the website and call center to "go live" or to posit that the generics' website/call center itself was not ready. Rather, he simply relies on the undisputed fact that the generics' website and call center were not ready to "go live" until, at the earliest March 5, 2013. (See Def.'s Opp'n, Ex. 14, Aff. of Robin Kinard ("Kinard Aff.") ¶ 32 ("Although the BTOD REMS program was approved on February 22, 2013, the program was not operational until a number **[*37]** of days later . . . until March 5, 2013.") He then applies his knowledge of well-settled FDA regulations to state that "the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date." (Fleischer Rep. ¶ 98.) Such an opinion could be helpful for a jury to understand the regulatory obstacles that might have prevented the generics from launching their products.

I also find no merit to the DPPs' argument that Dr. Fleischer's opinion is directly contradicted by Robin Kinard, who was in charge of actually developing the website and call center. As noted above, the DPPs argue that Ms. Kinard stated that if the generics were approved earlier, the website could have gone live earlier because some of the necessary "go-live" work was dependent on first getting REMS approval from the FDA. (Def.'s Opp'n, Ex. 29, Dep. of Robin Kinard ("Kinard Dep.") 115:1-25.) In her affidavit, however, Ms. Kinard admitted that the website and call center "were not operational until March 5, 2013." (Kinard Aff. ¶ 32.) Indeed, she averred that the original Project Addendum for the BTOD Rems did not anticipate **[*38]** launch of the website and call center components until one to two months after FDA approval of the REMS program. (*Id.* ¶ 33.)

Moreover, a closer look at Ms. Kinard's testimony reveals that she was more equivocal about the ability to go live earlier with FDA approval because she had not looked back to where the project was at the relevant time:

Q. Was PPD in a position—just assume that the REMS had been approved earlier, during some earlier period of time, okay? Say the REMS had been approved by the FDA according to, well, your original timeline, at the end of September. Could you have gone live prior to March 5, 2012?

A. I feel like I cannot answer that hypothetically because I'd have to know where we were in the process of that time, what was built, what wasn't built. I just don't feel like I can just answer that hypothetically. But I would say, if we were approved earlier, would we have probably have gone live earlier, yes.

(Kinard Dep. 115:13-25.)

Dr. Fleischer did, in fact, look back to that earlier time and noted evidence that BPMG did not begin work on the Go-Live requirements until the summer of 2012, and the website was an ongoing issue through August 2012. (Fleischer Sur-Rebuttal **[*39]** Rep. ¶ 22.) He further remarked that, even on February 15, 2013—a week prior to the generics' ANDA approval—the generics could not commit to a timeframe for completing the REMS website. (*Id.*) Based on that information, Dr. Fleischer opined that he "did not believe that the BPMG could have launched the mandatory website and call center in 1.5 weeks had Amneal and Actavis obtained ANDA approval in August or September 2012." (*Id.*) Given the less than certain nature of Ms. Kinard's testimony, I cannot find that it undermines Dr. Fleischer's report, such that I would exclude this opinion under Daubert. To the extent that the DPPs can prove—

either through Ms. Kinard's trial testimony⁶ or otherwise—that the generics' websites and call centers could have, in fact, been operational prior to March 5, 2013, those facts can be used on cross-examination to test the validity of Dr. Fleischer's opinion.

B. Opinions of Sheldon Bradshaw

The DPPs next move to exclude opinions offered by Defendant's expert Sheldon Bradshaw, who Defendant offers in rebuttal to the DPPs' expert, Professor Patricia Zettler.

The DPPs' expert, Professor Zettler, opines in part that (a) Defendant's conduct during the development [*40] of the shared REMS ("SSRS") for Suboxone and generic equivalents delayed approval of the SSRS until February 2013; and (b) it was false and misleading, in violation of various laws and regulations, for Defendant to claim that Suboxone film was less prone to misuse and better avoided pediatric exposures than Suboxone tablets. Mr. Bradshaw responds that (a) Defendant did not unduly delay in commencing SSRS negotiations with BPMG [Buprenorphine Products Manufacturers Group] generic manufacturers in First Quarter 2012; (b) Defendant's negotiating positions and conduct during SSRS negotiations in 2012 were objectively reasonable under the circumstances and did not delay generic entry; and (c) Defendant's marketing claims regarding tablets and film complied with FDA promotional standards.

The DPPs' challenge to Mr. Bradshaw's opinions is two-fold. First, they contend that Mr. Bradshaw impermissibly opines on the state of mind and subjective intent of Defendant and its employees during the SSRS negotiations. Second, they claim that Mr. Bradshaw improperly speculates that the FDA must have found that certain of Defendant's marketing materials complied with FDA regulations because it did not [*41] issue a Warning Letter or Untitled Letter.

1. Opinions as to Good Faith and State of Mind

The DPPs first argument challenges certain isolated portions of Mr. Bradshaw's 110-page report that project subjective motivations onto Defendant's actions. Three sets of statements are at issue:

#1 - Section III.E - "Reckitt Acted in Good Faith During SSRS Negotiations,"

214. Plaintiffs claim that Reckitt acted in bad faith by raising its various "gating" issues during SSRS negotiations with the BPMG generic manufacturers. However, the evidentiary record clearly negates such claims.

215. Robin Kinard, PPD's Senior Oversight Lead for the BTOD REMS project, was aware of Reckitt's SSRS positions and witnessed first-hand Reckitt's negotiation conduct with the BPMG generic manufacturers. She observed that: "Communications among BPMG members included debate regarding the contemplated REMS program. At times member companies disagreed regarding the merits of particular proposals. However, I do not recall any communications that I considered to be disrespectful or unprofessional. I also do not believe any participants in the BPMG meets were acting in bad faith. It is normal for manufacturers engaged in these [*42] kinds of joint projects to each advance its own positions.

⁶The DPPs contend that Dr. Fleischer admitted at deposition that because Ms. Kinard's company, PPD, was in charge of developing and launching the website and call center, Ms. Kinard was in a better position to testify as to how quickly the go-live requirements could have been completed. (Fleischer Jan. 7, 2020 Dep. 121:4-8.)

However, an expert will not be excluded "simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." **Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996)**. Rather, in the event that Dr. Fleischer and Ms. Kinard offer conflicting testimony on this subject at trial, it will be within the province of the jury to weigh their credibility, taking into consideration Dr. Fleischer's admission that Ms. Kinard is more qualified.

[sic] My observation is that each of the participants in the BPMG, including both Reckitt and the generic manufacturers, acted in good faith throughout the process."

216. Similarly, Kellie Taylor of the FDA also recognized that neither Reckitt nor the BPMG manufacturers were clearly to blame for the breakdown of SSRS negotiations. She testified that she "was aware of there being an inability to come to a single shared system REMS agreement" among the BPMG members, but felt "the cause of that inability . . . could [have been] on either side of the aisle . . . cooperation issues in a general sense."

217. Based on the testimonies of Ms. Kinard and Dr. Taylor, and my review of the contemporaneous documents, it is clear to me that the Reckitt's SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG's inability to create a single shared REMS system with Reckitt.

(Chiorean Decl., Ex. 4, Report of Sheldon Bradshaw ("Bradshaw Report"), ¶¶ 214-17 (internal citations omitted) (collectively "§ III.E").)

#2 - Other References to Defendant's "Good Faith" During SSRS Negotiations

- As Reckitt began to negotiate [*43] in good faith with the Generic ANDA Holders . . .
- Reckitt did not mislead FDA regarding . . . its willingness to negotiate with the ANDA applicants in good faith.
- Throughout the SSRS negotiations, Reckitt communicated to the FDA honestly about both the progress of its negotiations with the generic manufacturers and, despite its initial disinclination to participate in SSRS negotiations, the fact that it was negotiating in good faith with the ANDA applicants once it committed to participate in SSRS negotiations and not trying to drag out the negotiations.

(Id. ¶¶ 115, 222, 223 (collectively the "other good faith statements").)

#3 - Statements Regarding Subjective Motivations of the Parties

- The generic manufacturers preferred to save money.
- On June 13, 2012, Reckitt—concerned how the generic manufacturers had reneged on their promise to share up front cost for the BPMG REMS—sent a memorandum . . . to the FDA setting forth its concerns . . .
- To ensure that the generic manufactures [sic] took patents [sic] safety as seriously as Reckitt itself, Reckitt requested that the BPMG commit to signing a safety mission statement.
- The uncertain nature of the law of product liability made it [*44] important to try to gain a measure of clarity regarding how legal liability and litigation costs would be apportioned.
- When Reckitt was the sole manufacturer of [buprenorphine] products the company could influence the safety protocols in the opioid addiction disease space.

(Id. ¶¶ 119, 162, 167, 204, 208 (collectively, the "subjective motivation statements").)

The DPPs now contend that these state of mind and intent opinions are inadmissible because, as an expert, Mr. Bradshaw cannot offer testimony regarding someone else's state of mind. They posit that Mr. Bradshaw's reliance on Ms. Kinard's Affidavit is improper because Ms. Kinard admitted in deposition that she was not privy to much of the SSRS negotiations and could not speak to Defendant's internal discussions.

Defendant agrees with the DPPs that no expert may opine on the state of mind and subjective intent of Defendant, its employees, or any third parties. Defendant further represents that Mr. Bradshaw "will not be testifying to anyone's subjective state of mind," and agrees that references to "good faith" are inadmissible. (Def.'s Opp'n DPPs' Mot. 18.) Nonetheless, Defendant presses that Mr. Bradshaw should be able to testify [*45] as to objective facts.

It is well settled that experts may not provide testimony concerning "the state of mind" or "culpability" of defendants, corporations, regulatory agencies, and others. [*Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 661-62 \(E.D. Pa. 2012\)](#); see also [*Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 448 \(S.D.N.Y. 2011\)](#) (precluding an expert witness from testifying as to pharmaceutical company's bad faith). Indeed, the question of intent constitutes a "classic jury question and not one for experts." [*Robinson v. Hartzell Propeller, Inc.*, 326 F. Supp. 2d 631, 648](#)

(*E.D. Pa. 2004*) (citations omitted); see also *In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949, 2009 U.S. Dist. LEXIS 117355, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009)* ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'") (internal quotations omitted).

Here, several of Mr. Bradshaw's conclusions exceed these bounds. First, the entirety of Section III.E of his report is inadmissible because Mr. Bradshaw simply recites statements by Robin Kinard and Kellie Taylor to reach the conclusion that "Reckitt's SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG's inability to create a single shared REMS system with Reckitt." Such an opinion regarding intent is improper. (Bradshaw Rep. ¶ 217.) While Ms. Kinard's and Ms. Taylor's observations may potentially be introduced through their individual testimony, [*46] the jury must be free to draw its own conclusion about the import of those observations.

As to Mr. Bradshaw's "other good faith statements," I also find that they are inadmissible. These statements, embedded in longer paragraphs within Mr. Bradshaw's report, impermissibly ascribe to Defendant a subjective intent to negotiate in good faith with the generic ANDA applicants.

Finally, as to the alleged "subjective motivation statements," Mr. Bradshaw may certainly testify factually about various subjects such as potential litigation risks from safety concerns and factors that drug manufacturers consider in issuing public warnings about products. As such, wholesale exclusion of these statements is not warranted. Mr. Bradshaw cannot, however, suggest to the jury how those facts bear on the parties' subjective thought processes. Defendant has acknowledged this basic evidentiary rule and emphasized that Mr. Bradshaw's intended testimony will not delve into these subjects. Should the DPPs believe, however, that any question posed to Mr. Bradshaw at trial goes beyond permissible inquiries, they may of course object at that time.

2. Opinions About the FDA's Conclusions

The DPPs next argue that Mr. [*47] Bradshaw should not be permitted to mislead the jury about what the FDA did nor did not conclude about Defendant's marketing efforts. On this topic, Mr. Bradshaw's report states:

263. The record suggests that [the FDA's Office of Prescription Drug Promotion ("OPDP")] was in fact specifically asked (by FDA officials reviewing Reckitt's Citizen Petition) to review at least one exemplar of Reckitt's promotional messaging. . . .

264. Importantly, no action was taken by OPDP following this consultation (and, to date, Reckitt has not received either an untitled or warning letter concerning its marketing claims since the introduction of Suboxone Film in 2010). Based on my experience, this means that OPDP did not conclude that the materials violated FDA's advertising regulations. As Plaintiffs' expert correctly noted, when OPDP determines that promotional materials violated FDA's advertising regulations, it would send the drug sponsor a warning or untitled letter.

(Bradshaw Rep. ¶¶ 263-64 (emphasis added).)

The DPPs contend that, to the extent Mr. Bradshaw testifies that "no action was taken" by the FDA or OPDP, his opinion is false and misleading because the FDA took enforcement action against [*48] Defendant through a criminal investigation and resulting grand jury indictment based, in part, on Defendant's Suboxone marketing efforts. If Mr. Bradshaw's opinion is not excluded, the DPPs urge that a fair cross-examination of Mr. Bradshaw on his "cherry-picked account of the FDA's enforcement history" requires that evidence of the criminal investigation and indictment be admitted. (DPPs' Mot. 16.)

This argument is not the proper subject for a Daubert motion. The DPPs do not challenge Mr. Bradshaw's qualification to render this opinion, do not establish that Mr. Bradshaw's method in reaching the opinion is unreliable, and offer no challenge to the "fit" or relevance of this testimony to this case. Instead, the gist of the DPPs' motion is that *if* Defendant elicits testimony from Mr. Bradshaw on this topic, then the DPPs must be permitted to cross-examine Mr. Bradshaw on the criminal investigation and indictment to which the FDA contributed. This issue is better suited for a motion *in limine*.

Any mention of criminal proceedings could be highly prejudicial. Defendant, however, should be on notice that pressing Mr. Bradshaw to state that the FDA took no action in response to Defendant's [*49] promotional materials could open the door to appropriate rebuttal.

IV. THE STATES' MOTION TO EXCLUDE DR. DOLORES CURTIS

The States have filed a Daubert motion seeking to preclude the expert testimony of Defendant's expert Dr. Dolores Curtis. Dr. Curtis is President of Curtis Analytic Partners, Inc. ("CAP"), which specializes in marketing research and provides consulting services to small, mid-size, and large organizations in the healthcare business. (States' Mot., Ex. R, Rep. of Dolores Curtis ("Curtis Rep."), ¶ 1.) Dr. Curtis's report notes that, from 2004 through 2013, CAP provided both qualitative and quantitative marketing research services to Defendant. In connection with those services, CAP ran numerous marketing studies, many of which were focused on Suboxone film and tablets, in order to gauge prescribing and user preferences. (*Id.* ¶¶ 16-17.) These studies were conducted with physician prescribers and non-prescribers of Suboxone, as well as patient users and non-users. (*Id.* ¶ 18.) Based on the results of those studies, Dr. Curtis now offers three main opinions: (1) patients and physicians prefer Suboxone film over tablets; (2) the fact that film was often less expensive than generic [*50] tablets caused patients to favor Suboxone film; and (3) Defendant's disparagement of tablets over alleged safety concerns had a "relatively minor" impact on patient and physician preferences for film.

The States seek to preclude the entirety of Dr. Curtis's proposed testimony under all three of the Daubert factors. Primarily, they assert that she is not qualified to render the opinions proposed, and also contend that Dr. Curtis cannot reliably evaluate the methodology and statistical limitations of her surveys. Finally, the States posit that Dr. Curtis's testimony fails to "fit" under Daubert because it does not assist the trier of fact.

1. Qualifications

The States first contend that Dr. Curtis is not qualified to render the opinions proposed. She is a trained school psychologist with a master's degree in education, a graduate degree in school psychology, and a doctorate in philosophy. Currently, she owns a business focused on marketing surveys. According to the States, she has no statistical analysis training or experience, was uninvolved in the formation of the CAP surveys used, relied on others to do statistical analysis, does no such statistical analysis herself, and is not qualified [*51] from any medical perspective. The States posit that nothing in this background qualifies her to testify as an expert with respect to the accuracy of the methodologies used in the surveys, the statistical accuracy of the surveys, or the characteristics of Suboxone film or other drugs.

Defendant responds that Dr. Curtis easily meets the minimal standards of qualification under Rule 702. It points out that Dr. Curtis founded CAP in 1991, and she and her company have been conducting surveys ever since. In addition to the dozens of studies for Defendant alone, CAP has conducted hundreds of studies for other clients. Dr. Curtis herself played an active role in her company's projects, discussing project design, methodologies, timing, and execution with her staff project leads and reviewing all final reports prior to transmittal. Defendant presses that Dr. Curtis's decades of experience working on consumer research studies and surveys qualifies her to evaluate and opine regarding findings in the surveys at issue here.

"Qualification requires 'that the witness possess specialized expertise.'" Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008) (quoting *Schneider ex re. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)). As noted above, however, there is a liberal policy of admissibility and the Third [*52] Circuit has held that a "broad range of knowledge, skills, and training qualify an expert." *Id.* (quoting Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-42 (3d Cir. 1994)). The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." In re Mushroom Direct Purchaser Antitrust Litig., No. 06-620, 2015 U.S. Dist. LEXIS 120892, 2015 WL 5767415, at *3 (E.D. Pa. July 29, 2015) (internal quotations omitted). "If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility."

Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997) (citing *Paoli*, 35 F.3d at 741); see also *Hammond v. Int'l Harvester Co.*, 691 F.2d 646, 653 (3d Cir. 1982) (affirming admission of an expert on defective nature of farm equipment even though he had no formal schooling on the subject, but he had worked selling automotive and mechanical equipment, including agricultural equipment, and had taught automobile repair and maintenance at a high school).

I find that Dr. Curtis meets the liberal minimum qualifications to offer her statistical expert opinion on whether patients and physicians prefer Suboxone film over tablets, the impact of pricing of film and tablets on patient preference, and the impact of Defendant's safety messaging on patient and physician preferences for film. First, notwithstanding the states challenge to her lack of specialized education in statistics and the absence of a license at CAP for SPSS, (see States' [*53] Mot., Ex. D, Dep. of Dolores Curtis ("Curtis Dep."), 18:5-9, 32:4-15), Dr. Curtis's report explains:

My statistical training was during my master's and doctoral studies. At that time, I learned about and was trained on the utilization of psychological and counseling techniques requisite for evaluative purposes. On the quantitative side, I was schooled in the Statistical Package for Social Sciences ("SPSS"), as well as other survey-based statistical techniques including analysis of variance ("ANOVA"), chi-square, cross tabulations, P and F values, conjoint analysis, and univariate analyses. As such I am qualified as an expert witness.

(Curtis Rep. ¶ 19.)

At her deposition, Ms. Curtis testified that she understood how to do the statistical analysis and had training, despite the fact that she did not have broad educational background in statistics. (Curtis Dep. 132:2-21.) She admitted that she often plugged numbers into online tools, which "anybody can do," but clarified that the online tools were well-validated. (*Id.* at 132:22-133:25.) A jury may certainly find that, given Dr. Curtis's lack of more formal statistical training, her opinion is entitled to less weight. That factor, however, [*54] does not render her unqualified for purposes of exclusion under *Daubert*.

Second, as to her experience, the States press that Dr. Curtis was uninvolved in the formation of the surveys and is unqualified to offer expert opinion on the propriety of the methodologies utilized in the survey process. They posit that she did not consult with a statistician and that she personally does no statistical analysis, is not an expert in survey design or statistics, relies on the expertise of the in-house-lead of quantitative work, and only generally reviews what is suggested in research proposals. (*Id.* at 37:25-38:4, 39:14-19, 79:6-15.)

Dr. Curtis's report, however, suggests a broader involvement in statistical analysis. Dr. Curtis is the founder and, since 1991, has been the President of CAP. In that role, she oversees and assumes responsibility "for all qualitative and quantitative marketing research. This includes determining research design (along with [her] colleagues), establishing study leads, and assigning appropriate support staff and personal involvement in selected qualitative studies as appropriate." (Curtis Rep. 2.) She is accountable for all research aspects for studies in which she is [*55] personally involved and for studies implemented by other senior staff, and she is the key lead researcher on the majority of the qualitative studies conducted by CAP. (*Id.* ¶ 3.) As Dr. Curtis described her role:

After initially creating the idea of the business, I put together appropriate resources and key personnel staff that would allow the company to be successful and make our services known in the pharmaceutical healthcare marketplace. I also wrote or co-wrote every proposal that left CAP, including those for Reckitt. Prior to writing proposals, I discussed the potential projects with the CAP leads who would be assigned the projects should CAP be awarded the work. These discussions covered decision-making about appropriate methodologies, timing requirements, and overall execution responsibilities. In other words, I was always aware of how each study was designed, sampled, and undertaken. I was also regularly apprised of the status of each study. Regarding review of screeners or questionnaires for any of the quantitative studies where Dr. Piano was spearheading quantitative work, his co-lead on the study during that time, CAP's Vice President, Lori Gittleman, would address questions [*56] and/or review screeners or survey instruments as necessary. If there was a specific question or concern, I reviewed discussion outlines and survey instruments. I also typically reviewed all final reports prior to sending to end clients to ensure they met the research goals.

(States' Mot., Ex. S, Curtis Rebuttal Rep., ¶ 10.)

Finally, as to Dr. Curtis's reliance on her employees for statistical work, it is well recognized that, "[a]n expert witness is permitted to use assistants in formulating his expert opinion." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 612 (7th Cir. 2002). "Where the expert was directly involved with the research, analysis or drafting of the report, even with substantial assistance from a colleague or associate, his involvement in and knowledge of the report are matters of weight, not admissibility. Lee Valley Tools, Ltd. v. Indus. Blade Co., 288 F.R.D. 254, 266 (W.D.N.Y. 2013). Under these liberal rules of qualification, I find that Dr. Curtis indeed possesses the expertise necessary to testify as an expert on subject of consumer research studies and surveys.⁷ The arguments raised by the States are certainly fodder for cross-examination and may be fair grounds for challenging Dr. Curtis's credibility at trial. They are not, however, a basis on which to exclude her testimony entirely.

2. Reliability

The States [*57] next posit that the underlying surveys by Curtis Analytic Partners, Inc. ("CAP Reports") are fundamentally flawed, and therefore unreliable.

As set forth above, the reliability restriction requires that the testimony be based upon "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" and that the expert have "good grounds" for his or her belief." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). The rule does not require the party proffering the expert to demonstrate that the expert's assessment is correct. Paoli R.R. Yard, 35 F.3d at 744. Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion bears adequate indicia of reliability. Id. A flaw in methodology does not automatically disqualify an expert opinion; the flaw must be of such substance to create a lack of "good grounds" for the expert's conclusions. Id.

Dr. Curtis's report first provides an overview of the best practices used in a marketing research arena including: having specific goals, selecting samples that well represent the population to be studied, taking great care in matching question format and wording to the concepts being measured and the population being studied, pretesting [*58] questionnaires and procedures, using appropriate statistical analytic and reporting techniques, considering alternative data beyond a survey, using designs that balance costs with errors, training interviewers carefully on interviewing techniques and the subject matter of the survey, checking quality at each stage, maximizing cooperation or response rates within the limits of ethical treatment of human subjects, and developing and fulfilling pledges of confidentiality given to respondents. (Curtis Rep. ¶ 20 & n.6.) Dr. Curtis then goes on to discuss how the CAP studies met these best practices and explains that "[t]he research used random sampling of the target patient population and applied factor analysis, correlation, cluster analysis, Likert scales and open and closed-ended questions to address study objections." (Id. ¶¶ 21-24.) Finally, the report describes the primary research studies in detail, including the methodologies, sample sizes, relevant conclusions, and how Plaintiffs' experts misused these studies. (Id. ¶¶ 58-131.) The report also describes ten secondary supportive studies that bolster the primary studies. (Id. ¶¶ 132-47.)

Dr. Curtis then offers three opinions based [*59] off of the CAP studies. First, relying on seven different studies, including "the top five highest-powered physician and patient CAP studies," she opines that patients and prescribing physicians prefer Suboxone film over tablets. (Id. ¶¶ 27, 37.) Those studies had sample sizes of up to 500 participants, spanned a time frame of 2009 to 2013, and encompassed the views of both patients and physicians. (Id. ¶¶ 37, 40.) Dr. Curtis notes that the preference for film was largely based on two key factors, dissolution time and improved taste. (Id. ¶¶ 30-36.) Thereafter, Dr. Curtis looked beyond the CAP research studies and considered clinical trials, a 2012 peer-reviewed article, and surveys conducted by another marketing research firm, all of which

⁷ The States also argue that Dr. Curtis is also not qualified to draw conclusions about patients' or physicians' preferences from a medical perspective because she is not an expert in opioid use disorder and has no medical training. Defendant, however, does not offer Dr. Curtis as a medical expert, but rather as a statistical and consumer/marketing research expert. As such, I need not address this argument.

confirmed her conclusion that Suboxone film was a "dominantly preferred first-line therapy for most opioid-dependent patients." (Id. ¶¶ 154-61.)

Dr. Curtis's second opinion posits that, aside from patients' and physicians' preference for film, "[t]he combination of the generics' failure to offer a substantially cheaper medication with Reckitt's cost-saving coupon program made pricing preferences point in the same direction as product preferences—toward [*60] Film." (Id. ¶ 42.) Dr. Curtis cites to two January 2011 studies—one of 40 physicians and one of 300 physicians—which reflected that the most common reason for physicians prescribing the film was due to the coupon savings program. (Id. ¶ 47.)

Dr. Curtis's last opinion observes that "[w]hile the preference for and pricing of Film were the key drivers of treatment decisions, data indicates that any safety messaging associated with Film had a relatively minor influence on physicians' and patients' choice of prescriptions." (Id. ¶ 49.) This opinion relies on various preference studies among both physicians and patients which gauged what factors made film more attractive over tablets, and asked study participants to rank these factors. These studies, according to Dr. Curtis, consistently found that safety features such as child-resistant packaging and ease of abuse/misuse/diversion ranked lowest among the considerations. (Id. ¶¶ 49-57.)

The States now identify three purported flaws in Dr. Curtis's methodology, which they claim undermines the reliability of her opinions.

a. Bias in Methodology for Selecting Patients

The States first contend that participant selection in the various CAP surveys [*61] were deliberately biased in favor of those who preferred film. They claim that Dr. Curtis admitted that, with respect to one of the surveys at issue, someone who is happy with their Suboxone tablet and has never taken film would never make it into the survey. (Curtis Dep. 256:30-275:12.) The States then note that this sampling injects bias into the results,⁸ which render them unsuitable for making inferences about overall preference for film.

The States also criticize Dr. Curtis for not identifying generally accepted methods to reach her sweeping inferences about entire patient and physician populations. According to States' expert Nicholas Jewell, Dr. Curtis "does not demonstrate for *any* of the surveys she cites why the sample sizes were chosen as they were, or how the selected group of participants compare to the population at large, or how CAP accounted for response bias." (Jewell Rep., ¶ 60 n.87.) Moreover, States' expert Dr. Berndt opines that Dr. Curtis provides "little to no explanation of how the responses to these surveys were processed," including "the process of content analysis and response interpretation, thematic[] organization, employment of coding mechanisms, [and] thresholds [*62] of significance for anecdotal conclusions." (Berndt Rebuttal Rep. ¶ 81.) Absent explanations to address these concerns, the States posit that the quantitative methods CAP actually used remain a mystery.

The States' argument is flawed in several respects. Primarily, the States' criticism regarding bias in the reports is leveled at only a handful of the surveys relied upon by Dr. Curtis. Assuming *arguendo* that this criticism is accurate and creates bias in those identified surveys, this deficiency does not impact the entirety of Dr. Curtis's report, which relies on more than thirty different studies. For example, several of the surveys focused solely on *physician* samplings and why physicians prescribed either film or tablets. (Curtis Rep. ¶ 27-30.) Thus, the States' contention

⁸ (See States' Mot., Ex. B, Expert Rebuttal Report of Ernst Berndt ("Berndt Rebuttal Rep.") ¶¶ 76-79 ("For example, the 2011 Suboxone Film Post Launch Monitor excludes potential respondents that never took Film, so their preferences for taking and remaining on tablets are also excluded from the analysis. . . . This introduces sampling bias in the results, because the outcomes are based upon a non-representative sample of the population that would, on average, already exhibit a preference for Film."); States' Mot., Ex. J, Expert Report of Nicholas Jewell ("Jewell Rep."), ¶ 63 ("It is clear that physicians' opinions and practices were the driver in providing film experience for a significant number of respondents, a factor that has an indeterminate influence on patients' responses. However, it is reasonable to assume that this phenomenon will bias preference results in favor of film as the imposition of film by a physician brings with it the implicit (if not explicit) endorsement of the physician, potentially affecting a patient's preference for one formulation over the other.").)

that a certain *consumer* population was excluded would be irrelevant to such studies. Moreover, in one major study involving a sampling of 500 consumers, 377 individuals were currently using film with past tablet experience, 89 had past film experience of at least one week, and only 34 had started on the film with no tablet experience. (Curtis Rep., App'x B.19. at 5.) Finally, to the extent the States challenge surveys [*63] for not including patients who had never tried film, such a criticism would not impact the viability of a survey that sought information about what patients and doctors liked and did not like about tablets. (See Curtis Rep., App'x B.6, at 24 (physicians and patients did not like taste/aftertaste of tablets, the difficulty of keeping tablets under the tongue, or the fact that tablets break apart in bottles).)

More importantly, "mere technical flaws" in a survey's design or execution go to the weight to be afforded to the survey, not its admissibility. Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank of Evans City, 383 F.3d 110, 121 (3d Cir. 2004); see also Karlo v. Pittsburgh Glass Works, LLC, 849 F.3d 61, 83 (3d Cir. 2017) ("The question of whether a study's results were properly calculated or interpreted ordinarily goes to the weight of the evidence, not to its admissibility). Imperfections in the extent of a survey's universe—i.e., overinclusivity or underinclusivity—generally constitute technical flaws that do not undermine a survey's admissibility. Koninklijke Philips Elecs. N.V. v. Hunt Control Sys., Inc., No. 11-3684, 2016 U.S. Dist. LEXIS 84299, 2016 WL 3545529, at *6-7 (D.N.J. June 29, 2016). Stated differently, while a survey that excludes the *entire* relevant population may be so unreliable as to be inadmissible, see, e.g., Citizens Fin. Grp., 383 F.3d at 118-21 (upholding exclusion of consumer survey where interviewer polled consumers not located in the geographic area relevant to the facts of the case), a survey that [*64] is simply underinclusive or has other flaws in sampling remains admissible but subject to challenge. See, e.g., Hartle v. FirstEnergy Generation Corp., Nos. 08-1019, 08-1025, 08-1030, 2014 U.S. Dist. LEXIS 43033, 2014 WL 1317702, at *6 (W.D. Pa. Mar. 31, 2014) ("Defendant's arguments with respect to insufficient pretesting, improper information gathering, confusion by respondents, nonrepresentative and nonrandom sampling, hypothetical bias, error rate, and inconsistent and unconventional statistical analysis are 'technical flaws' that go to the weight rather than admissibility of the survey."); Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1143 (9th Cir. 1997) (finding that alleged leading questions and geographic limitation on survey respondents "go only to the weight, and not the admissibility, of the survey"); Jellibeans, Inc. v. Skating Clubs of Ga., Inc., 716 F.2d 833, 844-45 (11th Cir. 1983) (holding that "(1) poor sampling; (2) inexperienced interviewers; (3) poorly designed questions; and (4) other errors in execution" constituted "technical deficiencies" affecting the survey's weight).

Here, the deficiencies identified by the States are mere "technical flaws" that go to weight not admissibility. Defendant need not demonstrate the "correctness" of Dr. Curtis's opinion at this time. Thus, the States remain free to level their challenges to Dr. Curtis's opinion during cross-examination.

b. Bias from the "Here to Help" Program

The States' second reliability challenge contends [*65] that Dr. Curtis's opinions fail to analyze whether Defendant's "Here to Help" program biased survey responses. According to the States, many of the physicians and patients who took part in the CAP surveys were participants in Defendant's "Here to Help" support program that connected patients to doctors, reminded patients to keep appointments, educated and motivated patients, and reminded them to take their medication and refill prescriptions. After the launch of film in September 2010, Reckitt made the "Here to Help" program available only to film patients. In an internal email, James Piano—the lead statistician at CAP on whom Dr. Curtis relied—recognized that the "Here to Help" program skewed physician preferences for film over tablet.⁹ (States Mot., Ex. 24.) Yet, in her deposition, Curtis testified that she was "not a hundred percent certain of what the Here to Help program supported," did not analyze the extent to which the "Here to Help" program might have affected Suboxone sales one way or another, and did not analyze the extent, if any, that the "Here to Help" program might have driven Suboxone preferences one way or another. (Curtis Dep. 264:4-5,

⁹ Specifically, Piano commented: "We want to stress that the ratio of HTH [Here to Help] enrolled physicians to non-HTH enrolled physicians was 10 to 3 in this research: this inequality increased branded over generic preference in this sample compared to what would likely occur in the market. In forecasting preference shares this inequality overstates the share preferences for branded!" (States' Mot., Ex. 24.)

274:4-13.) Dr. Curtis also offered [*66] no opinion to assess the impact of Defendant's marketing activities for Suboxone film or tablets. (Id. 210:7-212:20.)

Contrary to the States' argument, however, this factor—noted in only one of the surveys reported on by Dr. Curtis—was specifically accounted for in Dr. Curtis's report. Dr. Curtis explained that this particular study, the Suboxone Preference Shares Among Physicians, was "an online quantitative study designed to provide insight into a number of objectives." (Curtis Rep. ¶ 58.) In a footnote, Dr. Curtis specifically commented that "[t]he study cautions that high ration of Here-to-Help enrolled physicians may increase branded over generic preference. To eliminate the effects of this preference, I will not comment on the portion of physicians who preferred branded medications over generics. However, this imbalanced preference would not affect results regarding the likes and dislikes of Film." (Id. n.80.)

Thus, Dr. Curtis specifically considered the impact of the "Here-to-Help" program and opined that it only impacted brand/generic preference, not film/tablet preference. To the extent the States' expert believes that the "Here-to Help Program" impacted the reliability of the [*67] study, it may raise this issue on cross-examination. See *Alco Indus., Inc. v. Wachovia Corp.*, 527 F. Supp. 2d 399 (E.D. Pa. 2007) ("As long as an expert's scientific testimony rests upon good grounds, based upon what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.") (quotations omitted).

c. Safety Messaging

Finally, the States challenge Dr. Curtis's opinion that "any safety messaging associated with Film had relatively minor influence on physicians' and patients' choice of prescriptions." (Curtis Rep. ¶ 49.) As a basis for this opinion, Dr. Curtis noted that a common question in the preference studies provided an "array of options for physicians or patients to choose from to gauge both (1) what factors made film more attractive over tablets, and (2) the relative importance of each factor." (Id. ¶ 50.) Using these questions, Dr. Curtis noted that safety was rarely the leading factor and, in some studies, ranked low as a secondary concern only on physicians' list of prescribing priorities. (Id. ¶¶ 50-51.) Moreover, Dr. Curtis remarked that studies documented that [*68] patients themselves were not influenced by safety claims and ranked safety factors among the lowest factors that prompted their choice of film over tablets. (Id. ¶ 52.) Finally, Dr. Curtis considered comments from physicians and patients on marketing surveys and observed that to the extent patients and physicians valued film's safety profile, "it was likely for reasons entirely unrelated to marketing" and instead based on experience. (Id. ¶¶ 53-54.)

The States contend that the CAP online questionnaires from which Dr. Curtis derived her opinion "cannot accurately measure the influences of safety concerns because *they simply do not ask about them*." (States' Mot. 19-20 (quoting Berndt Rep. ¶ 81) (emphasis in original).) They assert that absent direct questions about the impact, content, or frequency of safety marketing messaging to physicians or patients, Dr. Curtis cannot reliably testify that safety was a secondary concern and not the main driver of film prescribing.

The States' argument, however, is nothing more than a contention that there was, perhaps, a better way to gauge the impact of safety concerns on physician prescribing decisions. Such a criticism does not undermine the reliability [*69] of Dr. Curtis's methodology or her overall opinion. Indeed, Dr. Curtis discussed surveys that asked participating physicians to rank their preferences for various film attributes, and those that involved safety concerns repeatedly ranked lower on the list. From those surveys, Dr. Curtis fairly extrapolated a finding that safety concerns did not bear heavily on prescribing decisions. To the extent the States can challenge that opinion, such challenges are more appropriately raised on cross-examination or through rebuttal experts. See *AstraZeneca LP v. Tap Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 291 (D. Del. 2006) (admitting expert testimony on television survey despite opposing party's objection that survey did not address certain relevant questions because the objection "can effectively be dealt with on cross-examination, and thus goes to the weight, not the admissibility of the survey.").

3. Fit

The States' last challenge to Dr. Curtis's report asserts that she does not meet the "fit" requirement of Daubert. Specifically, the States argue:

Curtis's opinions are little more than a character reference for her colleague, and offer no expert testimony as it is traditionally understood—qualitative and quantitative opinions subject to evaluation and proof. Instead, they [*70] represent an attempt to end-run inadmissible hearsay into evidence, which is wholly improper. Curtis offers no reliable testimony about the methodology utilized in the studies; her use of them despite her lack of qualifications and sound basis to do so reveal "that there is simply too great an analytical gap between the data and the opinion proffered." Curtis' proffered three-page opinion regarding pricing preferences likewise has little or nothing to do with analyzing the survey data at issue. Parroting the survey conclusions without offering further analysis, and acknowledging that even the "opinions" that she offers unique to her reports (generic pricing) are "outside the scope of [her] quantitative surveys," she offers no actual relevant independent opinions. Thus Curtis's opinions fail the "fit" test of the Daubert standards for expert testimony.

(States' Mot. 20-21.)

The States' argument appears to misunderstand the subject of the "fit" inquiry. As noted above, the issue of fit "is one of relevance and expert evidence which does not relate to an issue in the case is not helpful." In re TMI Litig., 193 F.3d 613, 670 (3d Cir. 1999). To determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will [*71] help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 (3d Cir. 2020).

Dr. Curtis's testimony "fits" these proceedings. The States contend that a substantial portion of film prescriptions resulted from Defendant's false marketing/safety campaign. Dr. Curtis attempts to rebut this theory by opining that physicians and patients chose film for reasons other than safety. Thus, Dr. Curtis's opinions do, in fact, relate to an issue in this case.

For all of the reasons noted above, the States' Daubert Motion will be denied.

V. DEFENDANT'S OMNIBUS MOTION TO PRECLUDE EXPERTS

The next Daubert motion before me is Defendant's Omnibus Motion to Preclude certain of the opinions of the DPPs' experts Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot. Given the large range of expert opinions challenged, I address each expert individually.

A. Certain Opinions of Dr. Nicholas Jewell

Defendant first challenges certain portions of the opinions offered by the DPPs' expert Nicholas Jewell. (Def.' Omnibus Daubert Motion ("Def.'s Omnibus Mot."), Ex. 17, Report of Nicholas Jewell ("Jewell [*72] Rep.")) According to Defendant, there is extensive evidence, particularly in the form of two "RADARS studies,"¹⁰ indicating that film is less likely than tablets to result in pediatric exposures, or in abuse, misuse, or diversion. Dr. Jewell has been offered by the DPPs to rebut this evidence and opine that neither the available data nor the scientific publications interpreting this data provide a meaningful way to compare film and tablets. Defendant seeks to

¹⁰ RADARS refers to the Researched Abuse, Diversion, and Addiction-Related Surveillance program. (Jewell Rep. at n. 1.) RADARS I looked at the "Root causes, clinical effects, and outcomes of unintentional exposures to buprenorphine by young children." (Id.) RADARS II looked at "Abuse and diversion of buprenorphine sublingual tablets and film." (Id. at n.2.)

exclude two aspects of Dr. Jewell's opinions: (1) any efforts to compare film and tablets; and (2) opinions on the subjective states of mind of Defendant's expert witnesses and other scientists.

1. Comparisons Between Film and Tablets

At his deposition, Dr. Jewell was asked, "am I correct that you did not make any affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric?" to which he replied, "That was not part of my charge, and I don't have access to the information to complete that." (Def.'s Omnibus Mot., Ex. 22, Dep. of Nicholas Jewell ("Jewell Dep.") 24:24-25:6.) He also testified that he "was not asked to quantify or determine . . . the relative safety of [*73] any product" and did not make a determination, one way or the other, as to whether Film is more, less, or equally likely to result in pediatric exposures, as compared to tablet products." (*Id.* at 22:21-23:9.) Based on this testimony, Defendant now seeks to preclude Dr. Jewell from testifying that film is no safer than tablet products under any metric including pediatric exposures, abuse, and diversion. It also seeks to exclude any opinion from him that film is inferior in any respect to tablet products.

Dr. Jewell's expert report, however, does not attempt to opine that film is no safer than or inferior to tablet products. Rather, his report seeks only to identify flaws regarding the accuracy and reliability of the RADARS surveys upon which Defendant's experts rely to opine that film is safer. He summarizes his opinions, in pertinent part, as follows:

10. It is a basic axiom in the field of statistics that the conclusions that can be drawn from a statistical study or analysis are only as reliable as the data from which those conclusions are drawn. Here, as detailed below, the conclusions set forth in the RADARS I and RADARS II articles—including that Suboxone film formulation was 'safer' [*74] than the table formulation because the film 'caused' lower rates of adverse events than tablets—were unreliable from a statistical perspective because the conclusions were based on data that was of poor quality. The data do *not* allow accurate quantification of claimed safety improvements, nor reliable statistical inference regarding whether observed differences in adverse event rates are due to chance or other factors, as opposed to the formulation used or its packaging. As a result, no reliable conclusions could be drawn from the analyses in the articles, especially concerning an issue as complex and multi-faceted as causation. . . .

11. The conclusions in the RADARS articles were also unreliable because the analyses upon which they were based were not designed to draw reliable conclusions about issues such as causation—i.e., whether any observed differences in adverse events between the two formulations were due to, or caused by, differences in the two formulations, such as their packaging, or were due to chance or myriad other potential *confounding* factors. Even if we were to presume that the data used in the RADARS articles were reliable, the RADARS articles could do nothing more [*75] than generate a hypothesis about whether the film formulation caused a decline in adverse events. . . . Since no . . . robust studies were performed, no reliable statistical conclusions could be drawn in this case.

12. Similarly, the RADARS I and II articles both fail to establish the "root causes" of any claimed differences in the prevalence or rates of adverse events between the film and tablet formulations. In other words, the articles proving nothing about *what caused* such differences, and specifically whether such differences (if they existed) were due to the formulation used (film or tablet). . . .

(Jewell Rep. ¶¶ 10-12 (emphasis in original) (footnotes omitted).)

Dr. Jewell does not offer any independent scientific comparison of film and tablets. Instead, he relies on his statistical expertise to review and identify defects in the studies relied upon by Defendant's experts. In turn, he concludes that any opinions reached by Defendant's experts as to film's alleged superiority in terms of safety are not entitled to any weight. Such testimony is admissible. See [*Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc.*, 546 F. Supp. 2d 155, 168 \(D.N.J. 2008\)](#) (admitting expert who was proffered to identify methodological flaws in defendants' audit).

2. Subjective States of Mind [*76] of Defendant's Witnesses

Defendant also seeks to exclude Dr. Jewell's reports to the extent they seek to opine on the states of mind of Defendant's expert witnesses and other scientists. Specifically, in his report, Dr. Jewell opines that the RADARS studies suffer from a lack of independence from Defendant. (Jewell Rep. ¶ 40.) Dr. Jewell explains that:

13. [T]here was a distinct lack of independence between the scientific investigators who conducted the RADARS analyses and the research sponsors [Reckitt]. Indeed, the RADARS organization, in addition to receiving a \$ 75,000 from [Reckitt] for the RADARS I manuscript, received a subscription fee of \$ 650,000 from [Reckitt] for access to data (and hourly rates for any additional services). In addition, Venebio, [Reckitt's] paid consultant, worked closely with RADARS on the articles. These financial interrelationships—and the fact that [Reckitt] put substantial pressure on RADARS to complete work product by tight deadlines in order to achieve [Reckitt's] business objectives—call into question the reliability and objectivity of any conclusions reported in the RADARS articles.

14. Additionally, I have considered certain analyses that [Reckitt] [*77] funded, or performed, concerning comparative persistence and compliance rates between users of Suboxone film and Suboxone tablets. These analyses are also problematic in establishing any clear benefit of the Suboxone film formulation over tablets. Comparative data on persistence and compliance based on various forms of pharmacy and insurance claims data are insufficient to assess these concepts reliably, particularly in the absence of adjustment for differential patient costs. Even taken at face value, the results were equivocal with regard to any advantage of one Suboxone formulation over the other.

(Jewell Rep. ¶¶ 13-14.) Dr. Jewell goes on to expand in detail on this alleged bias in the substance of his report. (*Id.* ¶¶ 40-49, 96; Def.'s Omnibus Mot., Ex. 18, Nicholas Jewell Rebuttal Report ("Jewell Reb. Rep.") ¶¶ 11-12.) Defendant presses that such opinions must be excluded because lack of objectivity is a matter for the trier of fact to resolve and that expert witnesses who may not testify regarding intent, motive or state of mind.

To some extent, Dr. Jewell's opinion is properly focused on whether the surveys at issue were based on the "proper safeguards to insure accuracy and reliability." [*78] [*Pittsburgh Press Club v. United States*, 579 F.2d 751, 755-59 \(3d Cir. 1978\)](#) (noting that a statistically proper survey requires that: "[1] [a] proper universe must be examined and a representative sample must be chosen; [2] the persons conducting the surveys must be experts; [3] the data must be properly gathered and accurately reported; [4] the sample design, the questionnaires and the manner of interviewing [must] meet the standards of objective surveying and statistical techniques; [5] the survey must be conducted independently of the attorneys involved in the litigation; and [6] the interviewers . . . ideally should be unaware of the purposes of the survey or litigation") A substantial portion of Dr. Jewell's report opines that these specific safeguards were not in place in the RADARS I and RADARS II studies. (See, e.g., Jewell Rep. ¶ ¶ 40 ("although there are substantial limitations of any analysis of passive reporting data, one common advantage is that there is usually no relationship between the reporting system and the investigators analyzing the data. However, this firewall is not present here . . ."); ¶ 43 ("The relationship between [Reckitt] and Venebio [a separate consulting firm that collaborated with RADARS on Reckitt's behalf] was not independent [*79] in the sense of being at 'arms-length.'"); *id.* ("In my experience, it is unusual for sponsors to collaborate with researchers in funded academic research in such a way."). These opinions may be admissible, and Dr. Jewell can explain to the jury, from a statistical perspective, whether Defendant's involvement in and financing of the study violated these standards of accuracy and reliability.

To the extent, however, that Dr. Jewell seeks to venture beyond such opinions and testify that Defendant's experts and scientists were impartial or biased, such testimony will be excluded. See [*Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 440 \(D.N.J. 2009\)](#) (precluding pharmaceutical expert from testifying as to what pharmaceutical company was "trying" to do with its marketing strategy and what it believed was right or wrong); [*Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 433, 443 \(E.D.N.Y. 2011\)](#) (stating that the expert "walks a fine line between testifying as to what information is reflected in certain documents, and testifying to what certain individuals at Novartis thought about the information and their motivations for characterizing the information in a particular way"). Opinions regarding state of mind or intent are not permissible subjects of expert testimony. See [*In re Tylenol \(Acetaminophen\) Mktg, Sales Practices, & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 295 n.27](#) (collecting

cases holding that expert witnesses are not [*80] permitted to testify regarding intent, motive, or state of mind, or evidence by which such state of mind may be inferred).

Examples of such impermissible opinions are scattered throughout Dr. Jewell's report. By way of example, he opines that: "part of RADARS' interest in [Defendant] was presumably to encourage the pharmaceutical company to subscribe to their data resource efforts, thus supplying funds directly to RADARS," "it appears that [Defendant's] interest in RADARS I and II extended beyond simple research goals," and "[Defendant's] representatives were unhappy with the interim report on the RADARS project that was provided by Venebio on August 31, 2012, in part because of the delayed timing of completion of the final version of a RADARS I manuscript." (Jewell Rep. ¶¶ 40, 47, 49; see also id. ¶¶ 41, 44, 45, 46.) For the reasons set forth above, I will grant Defendant's motion to exclude any portion of Dr. Jewell's testimony that comments on state of mind.

B. Certain Opinions of Dr. Laurence Westreich

The next subject of Defendant's Daubert motion is Dr. Laurence Westreich, an associate professor of clinical psychiatry at NY Medical School. Dr. Westreich has peer reviewed more than [*81] a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. (Def.'s Omnibus Mot., Ex. 19, Rep. of Laurence Westreich ("Westreich Rep.") ¶¶ 5-18.) He offers four opinions: (1) Defendant did not have substantial scientific evidence to support its safety claims regarding Suboxone tablets as compared to film; (2) Defendant's statements that tablets presented a public risk because they had higher risks of misuse, abuse, diversion, and pediatric exposure than film would have been important to a reasonable Suboxone prescriber; (3) the expectation that tablets would be withdrawn from the market would have been important to a reasonable Suboxone prescriber; and (4) causing physicians to be suspicious of their patients and/or creating a conflict between physicians' and patients' interests would likely undermine patient treatment and medical outcomes and is therefore inconsistent with Reckitt's statements that it promoted Suboxone film in order to improve the patient experience and public health. (Id. ¶ 29.)

Defendant now argues that three portions of Dr. Westreich's report must be excluded. First, Defendant contends [*82] that the portion of the report regarding the "RADARS I" article was not prepared by Dr. Westreich and, therefore, he cannot testify as an expert regarding that article. Second, Defendant challenges Dr. Westreich's opinion that Defendant's marketing influenced other physicians. Finally, Defendant asserts that Dr. Westreich's opinions regarding subjective motivations should be excluded.

1. Opinions Regarding the RADARS I Article

Defendant first seeks to exclude the portion of Dr. Westreich's report that challenges the reliability and validity of the RADARS I study. As noted above, this analysis studied the "Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine in Young Children," and was published in the November 2013 volume of Journal of Pediatrics. (Westreich Rep. ¶ 122.) RADARS I concluded that "[e]xposure rates to film formulations are significantly less than to tablet formulations." (Def.'s Omnibus Mot., Ex. 27., at 1.) The DPPs rely on this study to support the fact that the switch to film was for procompetitive reasons. Dr. Westreich opines—over the course of sixteen pages and thirty-seven paragraphs—that multiple aspects of the RADARS study were [*83] problematic, thus affecting its reliability. (Westreich Rep. ¶¶ 122-58.)

According to Defendant, Dr. Westreich should be precluded from commenting on the RADARS study because he revealed, at his deposition, that he knew almost nothing about the RADARS I article. Specifically, when asked about it, the following exchange occurred:

- Q. Dr. Westreich, are you familiar with Exhibit 9 [RADARS I article]
A. I've seen this article, yes.
Q. Can you tell me—well, have you spent any time analyzing this article?
A. I have looked at it, yes.
Q. And have you come to any conclusions about it?

A. I want to make certain I know which article this is here. I've seen this article, but I haven't done a great deal of analysis of it.

Q. Okay. Have you examined—well how much analysis have you done of exhibit 9?

A. Not very much.

(Def.'s Omnibus Mot., Ex. 21, 201:12-202:2.) Defendant points out that during the course of this testimony, Dr. Westreich took multiple pauses and spent extensive amounts of time flipping through both the article and his report. (Def.'s Omnibus Mot., Ex. 86, Video Clip of Westreich Dep.) Indeed, Defendant notes that Dr. Westreich could not answer a simple question about "what data sources are [*84] used" in the article without taking additional time to look through the article. (Westreich Dep. 202:3-25.) From this, Defendant surmises that "[g]iven the extraordinary level of detail of [Dr. Westreich's] report [on RADARS I], Dr. Westreich's unfamiliarity with RADARS I at the deposition is utterly inconsistent with the notion that this portion of his report was 'prepared . . . by the witness' within the meaning of [Rule 26\(a\)\(2\)\(B\)](#)." (Def.'s Omnibus Mot. 9.) Defendant asserts that because Dr. Westreich clearly did not author this portion of the report, [Federal Rule of Civil Procedure 26\(a\)\(2\)](#) requires that it be excluded.

In response, the DPPs contend that various copies of the RADARS I article had been produced in varying formats throughout discovery, none of which say "RADARS I" in the title. Therefore, when first shown the article in his deposition, Dr. Westreich initially did not recognize it and needed to refresh his recollection. The parties took a break in the deposition, after which Dr. Westreich made a correction in his testimony, as follows:

A. I failed to identify one of the articles that I did look at in some depth which is the root cause, clinical facts and outcomes of unintentional exposure to buprenorphine in children. In [*85] fact, I wrote several pages in my report.

Q. Was the article unfamiliar to you when you saw it in this deposition?

A. Actually, the face of it was because it looked different as I was reading it. There's two Lavonas articles [RADARS I and RADARS II], so it was unfamiliar to me.

Q. Are you less familiar with the other Lavonas article?

A. Am I less familiar with the other one?

Q. Yes.

A. I don't believe so, no.

Q. How did it come to your attention that you had made an error on the record?

A. As you were asking me about it, it seemed very familiar, but since this one looked different, I wasn't able to identify it, and I realized that as we were talking.

Q. When we were off the record, did you have any conversation with anyone about this error in the record.

[Objection regarding attorney-client privilege]

(Westreich Dep. 212:10-213:23.) Plaintiff now argues that Dr. Westreich's "brief lapse of recall during deposition," particularly in the face of his sworn testimony that he recognized the RADARS I study and had discussed it in his report, does not warrant exclusion of this part of his report.

[Federal Rule of Civil Procedure 26](#) requires that expert reports be "prepared and signed by the witness. . . ." [Fed. R. Civ. P. 26\(a\)\(2\)\(B\)](#). Although the Advisory Committee [*86] Notes to [Rule 26](#) state that the Rule "does not preclude counsel from providing assistance to experts in preparing the reports," [Fed. R. Civ. P. 26](#) advisory committee's notes (1993), [Rule 26\(a\)\(2\)\(B\)](#) "does not contemplate blanket adoption of reports prepared by counsel or others. . . ." 6 James Wm. Moore et al., [Moore's Federal Practice](#) ¶ 26.23[4] (3d ed. 2000).

Dr. Westreich's report is 123-pages long and his reference to the RADARS study is extensive. Dr. Westreich's initial confusion certainly does not establish, under Daubert standards, that he did not prepare that portion of his report.¹¹

¹¹ I do not find Defendant's cited cases persuasive as each case involved either (a) an expert who admitted that he/she did not prepare certain portions of the report or (b) there was clear and convincing evidence that the expert did not prepare the report. I have neither scenario before me. See, e.g., [Numatics v. Balluff](#), 66 F. Supp. 3d 934, 941 (E.D. Mich. 2014) (excluding expert report where expert conceded at deposition that defendant's counsel wrote the expert report and the expert reviewed the draft of the 64-page report for only a couple of hours before signing it); [DataQuill Ltd. v. Handspring, Inc.](#), No. 01-4635, 2003 U.S. Dist.

Dr. Westreich's deposition reflects that he was originally unclear about the nature of the RADARS I report, but, after having an opportunity to review that report, he was able to quickly and directly answer multiple questions in detail about the study. (Westreich Dep. 202:19-211:17.) Immediately after questioning on that report, counsel took a break in the deposition. When the parties returned from the break, Dr. Westreich corrected his testimony—on the record and under oath—and stated that he had in fact reviewed the study in detail.

As noted by one district court faced with a similar allegation that an expert [*87] did not prepare his own report:

Litigation continually proceeds with assumptions that any witness, expert or otherwise, may have made different and sometimes inconsistent statements about relevant matters. The inconsistencies often relate to inconsequential details. They may also relate, of course, to material matters. Inconsistencies occur for various reasons. Memories dim. People make mistakes in recall. They sometimes speak carelessly, impulsively, and with little thought or discretion about their choice of language. They choose words which inadequately or inaccurately express what they mean to say. Trial courts often instruct juries, in weighing the credibility of witnesses, to consider whether their inconsistent statements relate to matters of material importance or of lesser consequence and whether they reflect either honest mistake on the one hand or an intent to deceive on the other.

The court generally would not disqualify a witness upon grounds he has changed his testimony after talking with an attorney. It would instead give opposing counsel the opportunity to cross-examine the witness. Effective cross-examination serves to expose inconsistencies of importance. It may also [*88] develop the extent to which a witness has been influenced by counsel to make changes in what he says. Similarly here. That a report of the expert has been revised, after a conference with the attorney, should not lead the court to hastily strike the designation of the witness. Defendant should instead find his recourse by cross-examination of the expert.

[*Marek v. Moore*, 171 F.R.D. 298, 301-02 \(D. Kan. 1997\).](#)

At trial, Defendant will be given significant leeway to further probe this issue before the jury and, if justified, re-raise its motion to exclude this portion of Dr. Westreich's testimony.

2. Opinions Regarding Influence of Defendant's Marketing on Physicians

Defendant next seeks to exclude the section of Dr. Westreich's report stating that "Reckitt's Film-superiority statements and withdrawal statements would have been important to the reasonable Suboxone prescriber." (Westreich Rep. § V.) In this section, Dr. Westreich opines that "[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical associations, and interacting with other doctors," the "average, reasonable" physician would be impacted and influenced by Reckitt's claims about the tablets' dangers, would have maintained [*89] an anti-tablet bias after generic tablets became available, and would have factored information about impending tablet withdrawal into their treatment decisions. (*Id.* ¶¶ 235-70.)

Defendant contends that such opinions regarding what other doctors deem material must be based on something more reliable than simply the expert's own experience as a doctor. Defendant asserts that a naked reference to "experience" is not a reliable methodology; rather the expert must explain how that experience leads to the

[*LEXIS* 2981, 2003 WL 737785, at *4 \(N.D. Ill. Feb. 28, 2003\)](#) (excluding expert testimony where expert admitted that plaintiff's counsel actually typed his report, large quantities of plaintiff's interrogatory responses appeared verbatim in the expert report, and expert did not even follow a proper infringement analysis); [*Play Visions, Inc. v. Dollar Tree Stores, Inc.*, No. 09-1769, 2011 U.S. Dist. LEXIS 61336, 2011 WL 2292326, at *9 \(W.D. Wash. June 8, 2011\)](#) (excluding expert report where expert admitted at deposition that counsel had just asked questions of the expert and filled in the answers on the report and that the expert did not see the final report until after it was circulated to the defendants; expert then submitted a "change" sheet after reviewing his deposition testimony which had "wholesale reversals of his testimony under oath" without any explanation); [*Stein v. Foamex Int'l, Inc.*, No. 00-2356, 2001 U.S. Dist. LEXIS 12211, 2001 WL 936566, at *5 \(E.D. Pa. Aug. 15, 2001\)](#) (excluding expert affidavit where expert never claimed to have played any substantial role in its preparation, other than signing it, and party offered no evidence that expert prepared affidavit in any meaningful way).

conclusion reached. According to Defendant, Dr. Westreich's report never explains how his experience leads to his conclusions and, as such, any statement as to what other physicians with certain information would think is purely speculative and not based on scientific knowledge.

The DPPs respond that Dr. Westreich's opinions are appropriately based on his decades of experience training medical students to treat addicted patients, as a psychiatrist making treatment decisions for patients, and as a peer reviewer of scholarly articles. The DPPs point out that Dr. Westreich also reviewed sufficient evidence, including Reckitt field reports and internal analyses about how doctors in fact reacted [*90] to the promotional statements, including a December 2010 Reckitt survey of 300 doctors about why physicians prefer Suboxone film over tablet.

Where traditional Daubert reliability factors are not workable, the Supreme Court has noted that the "relevant reliability inquiry concerns may focus upon personal knowledge or experience." [*Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150, 119 S. Ct. 1167, 143 L. Ed. 2d 238 \(1999\)](#). Indeed, expert testimony may be based on "experience alone—or experience in conjunction with other knowledge, skill, training or education." [*Fed. R. Evid. 702*](#), advisory committee's note 2000. "In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." *Id.*; see [*Kumho Tire Co.*, 526 U.S. at 156](#) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

With respect to the particular testimony at issue here, the Third Circuit has recognized that a doctor's experience alone renders him a reliable witness to testify about a reasonable standard of care or what a reasonable physician would do. [*Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405-07 \(3d Cir. 2003\)](#) (reversing exclusion of expert testimony about standard of care during pre-treatment for angioplasty). Consistent with that principle, numerous cases have held that a doctor may, based on his [*91] or her experience, "testify about what a reasonable doctor *should* know" or "how a reasonable doctor would interpret [a] safety warning." [*Bartlett v. Mut. Pharm. Co., Inc.*, 742 F. Supp. 2d 182, 196 \(D.N.H. 2010\)](#) (emphasis in original); see also [*In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-2641, 2018 U.S. Dist. LEXIS 9683, 2018 WL 495188, at *4 \(D. Ariz. Jan. 22, 2018\)](#) ("The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his opinion as to the information reasonable physicians expect to receive from IVC manufacturers, and whether physicians who implant IVC filters reasonably expect a properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring organs. "); [*Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 440, 443 \(E.D.N.Y. 2011\)](#) (finding that doctor could opine, based on professional experience alone, whether warning labels on drug were false or misleading from the perspective of a reasonable prescribing physician and whether certain information contained in drug company's internal documents regarding risks of drugs would have been useful to doctors in making prescribing decisions).

However, "most courts have prohibited experts from testifying 'about what all doctors generally consider in making prescription decisions' or about 'what doctors generally think,' unless the testimony is based on something more reliable than simply the [*92] expert's own experience as a doctor." [*Bartlett*, 742 F. Supp. 2d at 196](#) (quoting [*In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 U.S. Dist. LEXIS 9037, 2000 WL 876900, at *11-12 \(June 20, 2000\)](#)) (additional citations omitted); see also [*In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 302-03 \(D.R.I. 2019\)](#) (holding that doctor may not testify as to what all physicians do or consider in making prescribing decisions, but may testify as to his own prescribing decision-making process and knowledge, as well as that of his colleagues or other doctors with whom he has personal experience); [*In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 \(S.D.N.Y. 2004\)](#) ("Unlike opining about what physicians in general expect to see on a label, [expert]'s surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge."); [*In re Seroquel Prods. Liab. Litig.*, No. MDL 06-1769, 2009 U.S. Dist. LEXIS 126995, 2009 WL 3806436, at *8 \(M.D. Fla. July 20, 2009\)](#) (holding that expert doctors may express opinions regarding accuracy and adequacy of drug label without reference "to the asserted perceptions of other doctors" or whether doctors generally understand the contents of the label).

Here, Dr. Westreich's report tiptoes the line between properly opining how Defendant's marketing materials affected both his prescribing decisions and those of physicians with which he has had contact, and improperly speculating what impact those marketing materials had on the prescribing decisions of all physicians. To clarify where that line

follows, I hold that [*93] Dr. Westreich may testify that Reckitt's statements regarding safety risks of tablets versus film would be material to him and, in his experience, the reasonable Suboxone prescriber. He may not, however, testify that "when Reckitt Benckiser representatives reported that Suboxone Tablets were prone to inadvertent pediatric exposure, misuse, and diversion, doctors would of course assume that the generic buprenorphine/naloxone tablets would have the exact same set of side effects and adverse effects" and would "remain reluctant to prescribe buprenorphine/naloxone tablets of any sort." (Westreich Rep. ¶ 255.) Similarly, while he may opine about why he would not prescribe a medication that would soon be withdrawn from the market, he cannot opine that "[i]f a particular medication or preparation will soon be withdrawn from the market, most doctors would stop prescribing that medication[] to new patients and would start transferring their patients to other medications or preparations."¹² (Id. ¶ 268.) Thus, to the extent Dr. Westreich limits his testimony to what factors he considers in making prescribing decisions, it will be admissible.¹³ To the extent he seeks to speculate what other physicians [*94] generally did or would do, such testimony will be excluded.

3. Opinions Regarding Subjective Motivations

Defendant's final challenge to Dr. Westreich alleges that his opinions regarding subjective motivations should be excluded. Specifically, like Dr. Jewell, Dr. Westreich opines that researchers were biased due to their interactions with Reckitt. (Westreich Rep. ¶¶ 144-58, 189-92, 232.) Dr. Westreich also opines that Defendant's expert, Dr. Murrelle, "has a self-interest and motivation to not find any flaws with reports that his company [Venebio] . . . aided Reckitt in developing." (Def.'s Omnibus Mot., Ex. 20, Westreich Rebuttal Report ("Westreich Reb. Rep.") ¶ 32.)

As noted above, Dr. Westreich has peer reviewed more than a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. Thus, like Dr. Jewell, Dr. Westreich may permissibly testify, based on his experience in peer review, regarding whether the circumstances under which reports or other studies were prepared violated well-established safeguards on independent, accurate, and reliable studies.¹⁴

But Dr. Westreich also ventures into the impermissible [*95] territory of commenting on state of mind. By way of example, he states:

- "The documents indicate to me that Reckitt made clear to Venebio that Reckitt was 'the customer' and that the project's methodology and design should be tailored to Reckitt's specific 'business goals.'" (Id. ¶ 148.)
- "Furthermore, the documents indicate that, from the outset, the parties understood that Venebio would allow Reckitt to influence the paper's wording." (Id. ¶ 150.)

¹² The DPPs argue that Dr. Westreich has reviewed internal Reckitt documents, including the survey of how 300 doctors reacted to Reckitt's promotional statements, and as such, he is qualified to render opinions about physicians in general. I disagree. Dr. Westreich is a physician, not a statistician who has conducted extensive surveys about which he can testify.

¹³ Defendant also argues that Dr. Westreich's report is undermined by his own deposition testimony where he states that when teaching medical students or young doctors how to evaluate claims that drug manufacturers make about their products, he tells them to rely on research that has a solid scientific basis as opposed to marketing materials from the drug companies unless there is substantiation. (Westreich Dep. 138:16-140:21.) Any such contradiction between Dr. Westreich's opinion as to prescribing practices in his experience and Dr. Westreich's deposition testimony regarding such practices is not the basis for exclusion of his report, but rather is properly raised on cross-examination.

¹⁴ (See, e.g., Westreich Rep. ¶ 103 ("Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry."); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 ("From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis."); ¶ 155 ("documents extrinsic to the paper also show that it was finalized under extraordinary time pressures, which may also have contributed to data inaccuracies."); ¶ 189 ("as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse and Diversion study.").)

- "In my opinion, Reckitt's involvement in setting the project objectives, designing and implementing the protocols, and drafting the manuscript calls into question Venebio's statement in the published paper that 'The authors had full control of all aspects of study design, data collection, data analysis and management, and the decision to publish. Reckitt Benckiser Pharmaceuticals was able to review the manuscript only for proprietary information.'" (*Id.* ¶ 154.)
- "In my opinion, the references to 'getting the budgeting secured' and 'business usefulness' telegraph Reckitt Benckiser's desire to get results which would advance its business interests, or it would not fund the project." (*Id.* ¶ 191.)
- "Dr. Murrelle's bias in assessing his own [*96] studies also cannot be ignored. Since he is employed by the very entity whose research he is defending, and he produced the research himself, bias in favor of that research is inevitable. He has a self-interest and motivation to not find any flaws with reports that his company, Venebio, aided Reckitt in developing." (Westreich Reb. Rep. ¶ 32.)

Similar to my finding regarding Dr. Jewell, Dr. Westreich may not comment on state of mind or the credibility of Defendant's researchers and expert witnesses. See [*In re Seroquel*, 2009 U.S. Dist. LEXIS 126995, 2009 WL 3806436, at *8](#) ("[I]t is one thing for an expert to testify . . . to explain and compare information in Seroquel marketing materials to other evidence—and quite another matter for an expert witness to render an opinion concerning what a drug company intended or sought to achieve through the use of those marketing materials. The latter are proper subjects for closing argument, not expert testimony."). Accordingly, I will grant Defendant's motion to exclude any portion of Dr. Westreich's testimony that comments on subjective motivations.

C. Certain Opinions of Yvonne Tso

The DPPs have identified Yvonne Tso as an expert in managed care with different types of healthcare and healthcare-related experiences [*97] acquired over the course of thirty years. (Def.'s Omnibus Mot., Ex. 14, Report of Yvonne Tso ("Tso Rep.") ¶ 1.) Ms. Tso offers several opinions:

1. Reckitt's tablet withdrawal statements, public health risk statements, and pricing tactics would have been relevant to the typical, reasonable Managed Care Organization ("MCO") decisionmaker's decisions regarding film and tablet placement and likely resulted in decisions that gave film favorable formulary placement and blocked or restricted coverage for Suboxone tablets;
2. Reckitt's statements about tablet's higher risks of misuse, abuse, diversion, and pediatric exposure would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the purportedly less safe product (tablets) and favor the utilization of the purportedly safer product (film);
3. Reckitt's pattern of raising tablet prices during the pre-generic period, combined with eliminating tablet rebates, would place enormous economic pressure on the typical, reasonable MCO decisionmaker to make formulary adjustments to drive patients and doctors to film;
4. Reckitt's combined tactics from 2009 through 2012 would have been significant and material to a typical, reasonable [*98] MCO decisionmaker's formulary decisions to favor film and disfavor tablets, which in turn made tablets economically inaccessible to patients and imposed costly administrative burdens on doctors who prescribed tablets; and
5. Reckitt's conduct had the effect of entrenching film in the market, making it difficult for many MCOs to disfavor film on formularies after generic tablets entered.

(Tso Rep. ¶¶ 17-23.)

Defendant raises two challenges to Ms. Tso's opinions. First, it contends that Ms. Tso's bald invocation of her "experience" is not a basis for her opinions and, absent any testimony of her actual experiences, her methodology is unreliable. Second, it asserts that Ms. Tso ignored contrary evidence, thus rendering her opinions impermissibly speculative.

1. Invocation of "Experience" as Methodology

Defendant first challenges Ms. Tso's opinions about the materiality and causal effect of Defendant's alleged withdrawal and safety statements because such opinions are based solely on her "experience." According to Defendant, Ms. Tso did not conduct any type of survey to ascertain the impact of the communications at issue and has never asked anyone at a managed care organization ("MCO"), health [*99] plan, or pharmacy benefit manager ("PBM") about how they reacted to the alleged statements at issue. Defendants note that, at her deposition, Ms. Tso did not explain how her experience led to the conclusion reached, could not recall any of her actual experiences in determining formulary placements or other directly applicable experiences, could not remember examples of any analogous situations, and testified contrary to her own experience regarding safety claims.

While these alleged deficiencies may provide useful cross-examination, this challenge is an insufficient basis on which to exclude Ms. Tso's testimony. "The text of [Rule 702](#) expressly contemplates that an expert may be qualified on the basis of experience. "In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." [Fed. R. Evid. 702](#), Advisory Committee's Note (2000). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." [Id.](#) Repeatedly, courts have permitted experts to rely solely on their [*100] experience to opine on how a reasonable individual within the same industry would react. See, e.g., [In re Yasmin and YAZ \(Drospirenone\) Mktg., Sales Practices and Prods. Liab. Litig., MDL 09-2100, 2020 U.S. Dist. LEXIS 219949, 2011 WL 6302287, at *13 \(S.D. Ill. Dec. 16, 2011\)](#) ("As the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Dr. Kessler may testify about what a reasonable FDA official would have done with information about VTE adverse events."); [Krommenhock v. Post Foods, LLC, 334 F.R.D. 552, 579 \(N.D. Cal. 2020\)](#) (declining to exclude advertising expert opining, based on experience alone, about the impact that advertising has on consumer perceptions regarding the health and wellness benefits of consumer products generally and consumer behavior and decision-making as it relates to labeling claims on cereal packaging, even though expert did not conduct an focus groups or consumer testing); [Veleron Holding, B.V. v. Morgan Stanley, 117 F. Supp. 3d 404, 445 \(S.D.N.Y. 2015\)](#) (expert on banking industry standards "had worked in five of the preeminent firms in a highly competitive industry" and had "become acquainted with each firm's code of conduct during his years of service," so "the fact that he did not conduct a 'survey' before reaching his conclusion, or did not obtain a copy of every other bank's internal policies, is at best an avenue for cross-examination, rather than a disqualification from testifying.").

I find that Ms. Tso's testimony is [*101] permissible given the complex nature of formulary decisions by managed health care organizations. Ms. Tso may offer such opinions based on her experience as a retail and hospital pharmacist, in healthcare financing, and within managed care organizations where she was involved with all aspects of pharmaceutical benefit administration, formulary, and utilization decisions. (Tso Rep. ¶¶ 1-10.) Although she did not conduct any particular surveys, her experience alone qualifies her to opine on how Defendant's safety messages, tablet withdrawal statements, and practice of raising tablet prices would have factored into a reasonable, objective MCO decisionmaker's formulary adjustments. Ms. Tso also bolstered her opinion by citing to documentary and testimonial evidence that MCOs in fact made formulary decisions because of Defendant's withdrawal statements and claims that film was safer, and she explained the precise reasons how and why Defendant's actions impacted formulary and prescribing decisions. (Tso Rep. ¶¶ 38, 42, 53, 72, 74, 104, 115, 138, 150-51.)

Regarding Defendant's challenges to Ms. Tso's inability during her deposition to testify (a) about her actual experiences in determining [*102] formulary placement for these particular products, (b) in understanding what withdrawal or safety concerns were raised in her presence, or (c) even to identify examples of analogous situations, these are insufficient reasons for exclusion. Ms. Tso was able to identify several companies for she was involved in a formulary decision involving buprenorphine products. (Def.'s Omnibus Mot, Ex. 54, Dep. of Yvonne Tso ("Tso Dep.") 46:10-47:7.) She went on to state that "I don't think I can name all of them *because there are so many*." ([Id.](#) at 47:12-13 (emphasis added)). Although Defendant asserts that Ms. Tso had no recollection of her actual experiences in determining formulary placement for these products, my reading of her testimony differs. She explained that her experience with respect to buprenorphine drugs was so vast and varied, much of it occurring

years earlier, she simply could not recall the particulars for each of the discussions. (*Id.* at 49:7-56:24.) Any memory lapses as to specific conversations in years past are simply a basis for cross-examination.

I also find no merit to Defendant's allegation that Ms. Tso's opinion on the safety claims is belied by her testimony about her [*103] actual experiences. As noted above, Ms. Tso opined that Defendant's safety statements about the tablet would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the tablet. At her deposition, however, Ms. Tso testified that MCOs retain Pharmacy and Therapeutics committees to evaluate marketing claims by pharmaceutical companies and determine if they are corroborated by scientific studies. (Tso Dep. 72:3-73:9.) While such testimony perhaps affects the weight of her opinion, it does not, under Daubert standards affect its reliability.

2. Failure to Consider Contrary Evidence

Defendant's second challenge to Ms. Tso's testimony contends that she simply ignored contrary evidence regarding both alleged tablet-withdrawal and safety-claim statements. With respect to Defendant's alleged tablet-withdrawal communications, Defendant alleges that Ms. Tso failed to identify a single instance where a "withdrawal statement" caused any MCO to remove Suboxone tablets from a formulary. With respect to Defendant's alleged safety claims regarding tablets, Defendant argues that Ms. Tso (a) failed to explain why these communications did not deter commercial insurers from near-universal [*104] coverage of generic tablets, and (b) could only identify one MCO as having made a formulary decision based even in part on safety considerations.

Defendant's argument "reflects a fundamental confusion about the role of the court as a gatekeeper, under Daubert, to determine the admissibility of evidence, and the role of the jury, as a fact finder, to determine the weight to be accorded to admitted evidence." *ID Security Canada, Inc. v. Checkpoint Systems, Inc.*, 249 F. Supp. 2d 622, 691-93 (E.D. Pa. 2003). As has become a mantra throughout this opinion, the Supreme Court has admonished that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993); see also *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 427 (S.D.N.Y. 2016) ("To whatever extent Defendants' public or internal statements conflict with its experts' opinions or its litigation positions in these cases, that will be a problem for Defendants that Plaintiffs may exploit via cross-examination and argument. But Defendants' experts' failure to confront alleged conflicting statements . . . does not warrant exclusion under *Daubert*.").

As Ms. Tso's failure to address potential factual inconsistencies does not bear on the reliability of her testimony and [*105] may be tested through cross-examination, I will deny Defendant's *Daubert* motion on this ground.

D. Certain Opinions of Robert Verscharen

Defendant's omnibus *Daubert* Motion next challenges identified DPP expert Robert Verscharen. Mr. Verscharen—an individual with forty years' experience in the pharmaceutical industry—was retained by the DPPs as an expert on the business of pharmacy purchasing and dispensing of prescription drugs at the retail level. (Def.'s Omnibus Mot., Ex. 15, Robert Verscharen Report ("Verscharen Rep.") ¶ 1.) His report (1) describes the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution; (2) opines that the AB-rating is the linchpin of the savings to drug purchasers at all levels of the distribution chain; and (3) explains that therapeutic substitution is not as efficient or effective as AB-rated substitution in delivering cost savings to purchasers,

dispensers and consumers, and why a therapeutic substitution program to move prescriptions from Suboxone film to generic tablets, if it had been attempted, would [*106] have been inefficient and unsuccessful.¹⁵ (*Id.* ¶ 9.)

Defendants move to preclude these opinions on two grounds. First, to the extent that Mr. Verscharen claims that competition between film and generic tablets was hindered at the pharmacy counter due to the lack of automatic substitution, Defendant contends that the DPPs withheld evidence on this subject during discovery and may not now proffer an expert on this subject. Second, Defendant posits that Mr. Verscharen's opinion that "therapeutic substitution programs in general are difficult, inefficient, and rarely successful" lacks both an adequate basis and a reliable methodology.

1. Exclusion Based on Failure to Produce Evidence

Defendant first maintains that, during discovery, it requested that DPP class representative Meijer, Inc.—which runs a chain of pharmacies—produce "[a]ll documents relating to the switching between or among Buprenorphine Products" and documents relating to sales and communications regarding sales of these products. (ECF No. 178-1, Req. Nos. 2, 12, 14.) Presumably, Defendant requested this discovery because it bore on whether there was any antitrust impact resulting from Defendant's alleged actions. Meijer objected [*107] to such production, arguing that although documents relating to its purchases were relevant, "downstream discovery" relating to sales or interactions with consumers was irrelevant. In response to Defendant's motion to compel documents, Meijer produced a spreadsheet of invoice-level sales data going back seven years, including the date the prescription was filled, a description of the product dispensed, the manufacturer, the dispensed product identifying information, the co-pay information, the insurer or third-party payment information, any dispensing fee collected, any coupon used, the insurer or other carrier used, and an individual patient ID number to track any drug changes or changes in insurance over time. In response to further motion practice regarding this discovery, I found that Meijer's spreadsheet production satisfied their burden. (ECF No. 286-1). When Defendant sought additional information about downstream competition through a [Rule 30\(b\)\(6\)](#) notice issued to Meijer, Meijer refused to produce a witness on this subject. Defendant now speculates that "[i]t is highly likely that Meijer had responsive documents, as even Mr. Verscharen admits that pharmacies take vigorous efforts to inform [*108] consumers of the availability of generic products." It contends that the DPPs cannot offer an expert on a subject regarding which it withheld documents and testimony. (Def.'s Omnibus Mot. 22.)

Reviewing the document requests referenced by Defendant, I see no request directed specifically towards therapeutic substitution and whether it was effective in the absence of automatic substitution between AB-rated products. Moreover, it is not clear that Meijer had any such responsive documents. Indeed, Meijer's own [Rule 30\(b\)\(6\)](#) witness testified that Meijer had no policies directing substitution of a cheaper generic if the products were not AB rated:

Q. When a pharmacist is presented with a prescription, what should he do according to Meijer's policies?

A. Fill the prescriptions written.

Q. If the prescription is written using the brand name of a drug for which there are substitutes available, what does Meijer's policy direct the pharmacist to do?

...

¹⁵ Mr. Verscharen succinctly explained the difference between AB-rated substitution and therapeutic substitution. When a prescription has an AB-rated generic, the pharmacist has the authority, and in most states, the responsibility, to use a generic whenever available. If no AB-rated generic is available, then the pharmacist must fill the prescription as written.

In some limited instances, however, a pharmacist may attempt to do a therapeutic substitution. This may occur when a pharmacist receives a prescription for a brand name drug that does not have an AB-rated generic associated with it, but there may be another drug available with a similar therapeutic result that might provide benefits (economic or clinical) to the patient, as well as economic benefits to the pharmacy. This other drug would have a different chemical, dosage strength or dosage form, and would be dispensed in place of the originally prescribed product. For therapeutic substitution to occur, however, the pharmacist must call the doctor and have the prescription changed. (Verscharen Rep. ¶¶ 48-50.)

A. . . . If a generic is available, then it would be our pharmacists, within their rights to substitute a generic alternative to help save the patient money.

Q. Does Meijer have a policy regarding whether the pharmacist should do that?

A. No.

Q. Is the goal of [*109] Meijer's substitution to save the customer money?

A. Ultimately we are acting on the customer's behalf, and saving them money is very important, yes.

Q. So if a generic substitute is not cheaper, does Meijer have a policy whether or not the pharmacist should substitute in that circumstance?

A. No.

(Meijer 30(b)(6) Dep. 21:25-23:13.) Given such testimony, it is not clear what additional documents Meijer could have produced that Defendant would have used to rebut Mr. Verscharen's opinion that pharmacists can steer patients towards generic products.

As Defendant has not proven that DPPs failed to produce evidence bearing on the substance of Mr. Verscharen's report, I decline to grant Defendant's Motion on this ground. Should Mr. Verscharen testify at trial on subject areas which Defendant believes were the subject of valid but unresponded-to discovery requests, Defendant may raise a relevant objection at that time.

2. Opinions on the Difficult Nature of Therapeutic Substitution Programs

Defendant also objects on the grounds of qualification and reliability with respect to Mr. Verscharen's opinion that "[t]herapeutic substitution programs in general are difficult, inefficient, and rarely successful." [*110] (Verscharen Rep. § B.) Mr. Verscharen asserts that therapeutic substitution seldom occurs because of "the economics of pharmacy," which considers the difficulties and costs inherent in therapeutic substitution. Specifically, for therapeutic substitution to occur, the patient must be asked if they want the lower-cost generic, the pharmacist has to check insurance coverage, the pharmacist has to discuss costs and benefits with the patient, the physician must be contacted about the substitution and will often not be reached immediately, the pharmacist must document the revised prescription, and ultimately the new prescription must be transmitted to the store. (*Id.* ¶¶ 50-52.) Mr. Verscharen concludes that "the cost to the pharmacy of filling a prescription through a therapeutic substitution, under the best of circumstances (a centralized facility for such functions), is over \$ 8.00 prescription. This compares with no additional cost for filling a prescription through AB-rated substitution." (*Id.* ¶ 56.)

While such testimony in itself is admissible, the problem arises with Mr. Verscharen's subsequent opinion that a therapeutic substitution program to move prescriptions from Suboxone film [*111] to generic Suboxone tablets, if it had been attempted, would have been inefficient and unsuccessful. This is because his methodology in reaching this opinion relies on a single example of problems inherent in the therapeutic substitution program relating to the drug TriCor. He explains that, in 1998, Abbott Laboratories entered the market with the drug TriCor in capsule form, which did not have patent protection. (*Id.* ¶ 59.) In anticipation of threatened generic competition, Abbott developed a tablet form of Tricor which would be bioequivalent to, but not AB-rated with, the prior form, and it stopped selling its Tricor capsules. (*Id.* ¶ 60.) Thus, by the time generic competitor Teva obtained FDA approval for its generic capsules, the majority of Tricor prescriptions were for the tablets. (*Id.*) Because the capsules were not AB-rated to the tablets, Teva could not get automatic substitution at the pharmacy counter. (*Id.* ¶ 61.) Therefore, Teva decided to launch its capsule product as a branded generic drug, under the name Lofibra, and designed a therapeutic substitution program that encouraged pharmacies to contact physicians and convince them to change their Tricor prescriptions to the [*112] chemical name (fenofibrate) and in the capsule form. (*Id.* ¶ 62.) Teva paid for the program, but ended up cancelling it in less than six months because of a lack of pharmacy participation and/or conversions. (*Id.*) In addition, Teva faced competition from other generic companies who developed generic capsules that were AB-rated to the Lofibra tablets. (*Id.* ¶ 63.)

From this scenario, Mr. Verscharen opines that Suboxone presented similar problems with regards to the potential success of a therapeutic substitution program. (*Id.* ¶ 65.) He notes that tablets were not AB-rated to Suboxone film, so a therapeutic substitution program seeking to switch Suboxone film prescriptions to generic tablets "was likely to

fail," just as the program seeking to switch Tricor tablet prescriptions to capsules failed. (*Id.*) He explains that therapeutic substitution of generic tablets for Suboxone film would have been particularly difficult if, as Plaintiffs allege, there was a three-plus year campaign by Defendant to aggressively disparage the safety of tablets. (*Id.* ¶ 69.) Mr. Verscharen goes on to assert that "even in the unlikely event that a therapeutic substitution program involving Suboxone was attempted, [*113] it is a virtual certainty that the program would result in far less savings to purchasers (including patients) than automatic AB-rated generics would have produced if Defendants had not engaged in the challenged scheme." (*Id.* ¶ 70.) Finally, he opines that if therapeutic substitution were to become the norm in the pharmaceutical industry, it would result in lower generic substitution and higher prices to consumers because of the cost to the pharmacy of engaging in the therapeutic substitution process.

I do not find that Mr. Verscharen's methodology fits the facts of this case. As set forth above, to determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." [Fed. R. Evid. 702\(a\)](#). Had Mr. Verscharen applied his experience in the pharmaceutical industry to the particular facts here—*i.e.*, whether a generic manufacturer of buprenorphine naloxone tablets could have successfully launched a therapeutic substitution program for prescriptions written for branded film—his opinion may have helped the trier of fact. However, Mr. Verscharen premised his opinion on only general pharmaceutical experience [*114] and a single example from more than a decade earlier when a different generic company's effort to launch a therapeutic substitution for a different drug under different circumstances was unsuccessful. Such an example, while perhaps identifying pitfalls and obstacles in that program, does not easily translate to the same pitfalls and obstacles in a therapeutic substitution program here. Mr. Verscharen had no idea of what Plaintiff Meijer did to switch prescriptions between film and generic buprenorphine naloxone tablets and made no effort to understand Meijer's opinions and experience. (Def.'s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen ("Verscharen Dep.") 113:2-23.) He also did not (a) address whether generic manufacturers thought that pharmacies could effectively help switch prescriptions to generics, (b) review any documents from the record regarding how generic manufacturers understood the competition between their products and the film product, or (c) look to see whether the generic manufacturers here tried to advertise their products. (*Id.* at 116:20-117:11.) Finally, Mr. Verscharen admitted that he had done no analysis of how branded Suboxone film compared to generic buprenorphine [*115] naloxone tablets with regard to any measure of price or profitability and could not say whether patients would typically pay more for film as compared to generic tablets. (*Id.* at 109:6-111:14, 126:6-130:7.) Indeed, at no point did Mr. Verscharen evaluate whether a medicine designed to combat opioid addiction would be suitable for a therapeutic substitution program. (*Id.* at 115:12-18.)

Moreover, even if Mr. Verscharen's testimony could satisfy the "fit" element of Daubert, I cannot find that his methodology on this issue is sufficiently reliable. For witnesses relying solely or primarily on experience, as Mr. Verscharen does here, "then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for an opinion, and how that experience is reliably applied to the facts." [Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc.](#), 546 F. Supp. 2d 155, 165 (D.N.J. 2008) (citing [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), 43 F.3d 1311, 1319 (9th Cir. 1995)). Mr. Verscharen, however, fails to connect his experience to his opinion. In fact, in his deposition, Mr. Verscharen revealed that his *actual* experiences belie his opinion that a therapeutic substitution for buprenorphine naloxone products would not work. He testified that he developed and worked in a Therapeutic Intervention Center for Thrift Drug, [*116] which was a department consisting of technicians and pharmacists that contact patients and physicians about programs or about products that they feel the physician and the patient should be aware of, and was designed to ensure that pharmacy stores were not taking the time "in doing some of the things that I wanted to communicate to physicians and patients." (Def.'s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen ("Verscharen Dep.") 89:6-24.) More specifically, in lieu of an individual pharmacist engaging in the therapeutic substitution process described above, the center was staffed with approximately thirty technicians who would contact patients about potential cost savings in using a biosimilar drug and, if the patient approved it, the technicians would call the physician and get him/her to change the prescription. (*Id.* at 131:8-133:9.) This Therapeutic Intervention Center actually eliminated the precise time and cost factors at the store level that made the Tricor therapeutic substitution unworkable—factors which Mr. Verscharen now opines claims would make therapeutic substitution unworkable here.

In short, Mr. Verscharen's opinion is not an expert opinion, but rather a personal [*117] opinion based on one experience with a generic company trying a similar therapeutic program. He made no effort to specifically apply the factors at issue in that program to the unique circumstances of this case. Accordingly, I find that Mr. Verscharen can testify about the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution. (Verscharen Rep. ¶¶ 16-44.) He can also discuss the efficacy of automatic AB-rated generic substitution and the hurdles he specifically experienced in therapeutic substitution programs. (*Id.* ¶¶ 45-64.) He may not, however, make the speculative leap—as he does in his report—that similar problems would have likely rendered unsuccessful a therapeutic substitution program regarding Suboxone. Accordingly, I will grant this portion of Defendant's Motion.

E. Opinions By Patricia Zettler

Defendant moves to exclude the report of Professor Patricia Zettler, who opines that: (1) Defendant's involvement with the development of shared REMS with the generics directly delayed approval of that shared REMS; (2) had Defendant [*118] informed the FDA and the generics on January 12, 2012 that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted BTOD SSRS, six months earlier than actual approval was obtained; (3) Defendant's promotion of the Suboxone film as less prone to misuse, diversion, and pediatric exposure than the Suboxone tablet was false or misleading in violation of the [Food, Drug & Cosmetic Act's \("FDCA"\)](#) and FDA's regulations because the claims were not supported by statistically significant data at the time; and (4) if she were an attorney counseling a drug sponsor client in the position of Defendant, she would have advised her client not to make such safety claims.

Defendant challenges Professor Zettler's first and second opinions on two grounds.¹⁶ First, Defendant argues that Professor Zettler has no expertise regarding how long it takes to assemble an approvable REMS submission, nor does she report any expertise that would inform the assumptions underlying her timeline. Second, Defendant contends that Professor Zettler provides no methodology beyond "wishful thinking."

1. Qualification

Professor Zettler graduated law school in 2009 and then worked in the Office [*119] of the Chief Counsel at the FDA for just under four years, after which she became a law school professor. Given that background, Defendant contends that her practical experience is limited. Citing to her deposition, Defendant notes that Professor Zettler has never advised a pharmaceutical manufacturer or client on proposed promotional messaging, never advised a pharmaceutical manufacturer or client regarding issues pertaining to a shared REMS program, and never served as an expert witness before. (Def.'s Omnibus Mot., Exs. 23-24, Dep. of Patricia Zettler ("Zettler Dep.") 212:20-213:24.) Defendant also points out that Professor Zettler was never involved in any decision to grant a waiver from a shared REMS requirement and never worked on any shared REMS programs in which a waiver was requested. (*Id.* at 72:13-73:12.) Finally, although she reviewed and commented on REMS for the FDA, Defendant notes that she never drafted any REMS documents for the FDA and could not recall instances of dealing with a schedule by which manufacturers had to put together REMS documentation, (*Id.* at 288:10-294:10.) Defendant argues that Professor Zettler is not qualified to render an opinion on how long the [*120] shared REMS should or could have taken.

Defendant improperly truncates Professor Zettler's experience. She is a lawyer, who served as associate chief counsel in the U.S. Food and Drug Administration's ("FDA") Office of the Chief Counsel, where she advised on various issues including drug safety, prescription drug advertising and promotion, clinical investigation oversight, drug labeling, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, incentives for developing antibiotics, and advisory committees. (Def.'s Omnibus Mot., Ex. 1, Patricia Zettler Rep. ("Zettler Rep."),

¹⁶ Defendant also challenges Zettler's third and fourth opinions above, but raises them in the context of its "Motion to Exclude Plaintiffs' Expert Opinions Asserting or Relying Upon Assertions that Alleged Reckitt Safety Messages Were 'False,' 'Misleading,' 'Disparaging,' 'Fabricated,' 'Fraudulent,' 'Sham,' or 'Deceptive.'" I discuss these arguments *infra*.

¶ 1.) While at the FDA, REMS were one of her areas of specialization, and she "regularly met with agency personnel in the Center for Drug Evaluation and Research (CDER) involved with REMS, including personnel in CDER's Office of Regulatory Policy and Office of Surveillance and Epidemiology, provided advice on REMS for specific drugs and drug classes, including REMS with elements to assure safe use and single shared systems (SSRS), and reviewed and revised agency documents related to REMS." (*Id.* ¶ 9.) In addition, Professor Zettler specialized in prescription drug advertising and promotion, [*121] and she regularly provided advice on the FDA's policies for prescription drug advertising and promotion and whether drug companies' promotional activities violated relevant provisions of the FDCA and the FDA's implementing regulations. (*Id.* ¶ 10.)

After leaving the FDA, Professor Zettler served for two years as a Fellow and Lecturer at Stanford Law School where she conducted research on FDA regulation of drugs and devices and co-taught the law school's Food and Drug Law course, which covered, in part, the FDA's requirements for REMS and prescription drug advertising and promotion. (*Id.* ¶ 7.) She also worked as a professor at Georgia State University College of Law and, currently, at The Ohio State University College of Law, where she has continued to develop an expertise in FDA regulation, including the FDA's requirements for REMS and prescription drug advertising and promotion. (*Id.* ¶ 11-12.) From 2016 to 2017, Professor Zettler served as a consultant to the National Academies of Sciences, Engineering, and Medicine's Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse, where she provided advice on the FDA's authority over and the regulatory history [*122] for prescription opioids, including issues associated with REMS and prescription drug advertising and promotion.¹⁷ (*Id.* ¶ 11.)

Given this extensive background, I have little trouble finding that Professor Zettler may render the opinions in her report. As repeatedly emphasized, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." [*Kannankeril v Terminix Int'l*, 128 F.3d 802, 809 \(3d Cir. 1997\)](#).

2. Methodology

In January 2012, the FDA asked all generic manufacturers of buprenorphine medications to collaborate with Reckitt on a single, shared REMS ("SSRS") by May 5, 2012. Given the contentious nature of the negotiations, the generic manufacturers submitted a proposed generics-only REMS, which the FDA rejected as inadequate. From that initial submission to approval, another 188 days passed due to additional deficiencies identified by the FDA. Professor Zettler opines that had Reckitt informed the FDA and the generics at the start of the REMS process, on January 12, 2012, that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted [*123] BTOD SSRS six months earlier than actual approval was obtained.

Defendant contends that Professor Zettler's methodology in reaching this opinion is unreliable because the opinion rests on four assumptions: (1) the FDA would accept Reckitt's hypothetical refusal to negotiate rather than continuing to ask Reckitt to engage in negotiations; (2) after a Reckitt refusal to negotiate, it would take the FDA only twelve days to inform the generics that the FDA was willing to consider a waiver-granted SSRS, meaning that the generics could file their own REMS safety plan independent of Reckitt; (3) although the FDA had set a 120-day deadline for the submission of REMS documentation, the generics would have beaten the deadline by almost two months; and (4) instead of 188 days passing between the generics' initial submission and approval of their REMS,

¹⁷ During her deposition, Professor Zettler expanded on her FDA experience. (Zettler Dep. 38:15-40:19.) With respect specifically to shared REMS programs, Professor Zettler noted that she "provided legal advice on any issues that came up with those particular REMS . . . [and on] whatever legal issues might have come up for the agency" and specifically identified two REMS that she worked on with elements of shared safe use and single shared systems. (*Id.* at 60:3-61:12.) To the extent Defendant argues that Professor Zettler did not work on a waiver request while at the FDA, the DPPs accurately note that the SSRS waiver in this case was the first ever granted and it occurred just months before she left the FDA in 2013. (*Id.* at 273:6-274:11.) Nonetheless, based on her experience, she was able to discuss the waiver statute and its requirements. (*Id.* at 274:4-278:20, 284:6-286:22.)

the time interval instead would have been only 165-175 days. Taking each assumption individually, Defendant attempts to debunk the opinion's validity and argues that Professor Zettler has no qualification or methodology by which to reach these various conclusions.

Defendant's challenge is an effort to establish facts before a jury rather than a proper [*124] Daubert attack on an expert's reliability. The Third Circuit has recognized that an expert may construct—as Professor Zettler does here—a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened 'but for' the defendant's unlawful activities." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 292 (3d Cir. 2012) (quoting *LePage's Inc. v. 3M*, 324 F.3d 141, 165 (3d Cir. 2003)). When certain facts underlying the "but-for" world are in dispute "experts sometimes reach different conclusions based on competing versions of the facts. The emphasis . . . on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other." *Fed. R. Evid. 702*, Advisory Committee's Notes (2000). In other words, *Daubert* "does not preclude testimony merely because it may be based on an assumption." *In re TMI Litig.*, 193 F.3d 613, 677 (3d Cir. 1999) amended *199 F.3d 158 (3d Cir. 2000)*. Rather, contentions that an expert's assumptions are unfounded go to the weight, not the admissibility, of the testimony. *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996).

I find that Professor Zettler's methodology meets the standard of reliability as she analyzed the real-world timeline of the SSRS-related activity, applied her knowledge of and experience with FDA policy and practice, and adjusted that timeline [*125] to reflect a world in which Defendant promptly refused to participate and was not involved in SSRS negotiations. Her report encompasses her review of Defendant's internal planning documents, FDA communications, and generic actions and then constructs a detailed timeline of actions by Defendant that, in her opinion, delayed approval of the REMS. (Zettler Rep. ¶¶ 118-135.) Her report also describes, based on various communications and events, the timeline for the generics' development of a single shared REMS had Defendant informed the FDA that it did not intend to participate in a single shared REMS on or about January 12, 2012. (*Id.* ¶¶ 136-43.) To the extent Defendant believes that Professor Zettler's underlying assumptions are factually inaccurate or disproven by the evidence, it may raise those issues on cross-examination.

F. All Opinions By Deborah Jaskot

The final expert which Defendant individually challenges is Deborah Jaskot. Ms. Jaskot is a pharmaceutical industry consultant who has overseen and submitted hundreds of ANDAs to the FDA for review and approval. Based upon her thirty-plus-years' experience in the pharmaceutical industry working on FDA regulatory matters, her knowledge [*126] of FDA regulations and practices, and her review of the evidence in this case, she offers two opinions. (Def.'s Omnibus Mot., Ex. 10, Deborah Jaskot Report ("Jaskot Rep.") ¶ 18.) First, she avers that if the REMS and REMS-related labeling of the generics' ANDAs were approved by the FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame. (*Id.*) Second, she opines that Reckitt's September 25, 2012 Citizen Petition was deficient in multiple respects and the specific requests therein stood no reasonable chance of being granted. (*Id.* ¶ 19.) Defendant challenges both opinions.

1. Opinion on the "But-For" ANDA Approval Date

Defendant first contends that Ms. Jaskot has no foundation for her opinion that "but-for" Defendant's delay during the shared REMS, generic manufacturers Amneal and Actavis would have had their ANDAs for generic tablets approved between August 22, 2012 and September 1, 2012. Defendant reasons that a condition of approval of ANDAs is that the facilities that make both the finished product and its active ingredients comply with FDA regulatory [*127] requirements, namely the "Current Good Manufacturing Practices" ("cGMPs"). (*Id.* ¶ 44.) According to Defendant, however, both Actavis' supplier of active ingredients and Amneal's contract manufacturing facility were not cGMP-compliant as of September 1, 2012. Specifically, Defendant notes that (1) Actavis' ANDA relied upon active ingredients supplied by a facility operated by a contract manufacturer, Macfarlan Smith, which the

FDA purportedly found had "objectionable conditions and practices" during an April 2012 inspection, and (2) Amneal's supplier of buprenorphine was not compliant with FDA regulations as of October 2012.

The DPPs respond that Ms. Jaskot's review of documents and application of her experience reveal a contrary conclusion: that there would have been earlier cGMP approval of both Actavis' active ingredient supplier and Amneal's contract manufacturing facility. The DPPs note that Ms. Jaskot details how cGMP inspections are conducted, how an FDA project manager ushers an ANDA through the FDA approval process, and why the Actavis supplier compliance status would have been found acceptable earlier had the rest of the ANDA been ready for approval between August 22 and September [*128] 1, 2012. (Def.'s Omnibus Mot. Ex. 15, Deborah Jaskot Rebuttal Report ("Jaskot Reb. Rep.") ¶¶ 59-63, 67-69.) In addition, the DPPs contend that Ms. Jaskot directly disputed that there was a compliance impediment with Amneal's contract manufacturing facility that would have prevented approval of Amneal's ANDA before September 1, 2012. (*Id.* ¶¶ 39-40.)

Faced with a similar Daubert objection predicated on disputed evidence relied upon by the expert, the Third Circuit instructed:

An expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury. It is also, as the District Court observed, a proper subject for cross-examination. . . . [F]actual disputes are for the jury, and [plaintiff] was perfectly free to explore on cross-examination the reliance placed by [the expert] on the disputed facts and to argue to the jury that, if it rejected the underlying factual premises of his report, it should also reject [the] expert opinion . . .

[*Walker v. Gordon*, 46 F. App'x 691 \(3d Cir. 2002\).](#)

Here, the parties' disagreement is a dispute of fact not an issue of reliability under Daubert. Such disputes must be resolved by a fact-finder at trial, and, as such, I decline [*129] to exclude Ms. Jaskot's testimony on this ground.

2. Opinion on Reckitt's September 2012 Citizen Petition

Defendant also challenges Ms. Jaskot's report to the extent she offers the following opinion on Defendant's Citizen Petition:

It is furthermore my opinion that Reckitt Benckiser's September 25, 2012 Citizen Petition was deficient in several respects and the specific requests therein stood no reasonable chance of being granted because: (i) RB's request that generic applicants be required to engage in the same voluntary education practices as RB had no statutory support—the applicable statutes, regulations, and FDA practices only mandate that the labeling of generic drugs mimic the involuntary mandated labeling of the corresponding brand drug (with certain minor exceptions not applicable here); and (ii) RB itself admitted that the studies upon which it was relying for its requests that (1) FDA not approve ANDAs lacking unit-dose packaging and (2) FDA determine that Suboxone tablets were discontinued for reasons of safety, were incomplete, and thus, by definition, could not satisfy FDA's statutory requirements. Therefore, it is my professional opinion that each of the three specific [*130] requests in the Petition were factually and legally baseless, and that no reasonable petitioner could expect those requests to be granted. Furthermore, if I had been in charge of overseeing the filing of Citizen Petitions at Reckitt Benckiser at the time, I would not have signed or agreed to file the September 25, 2012 Petition.

(Jaskot Rep. ¶ 19.)

Defendant contends that Ms. Jaskot's opinions are inadmissible on three grounds: (1) her opinion as to the purported "baselessness" of the Citizen Petition is an impermissible legal conclusion; (2) she admits to being unqualified to opine on the scientific basis of Defendant's Citizen Petition requests; and (3) her regulatory opinions fail to fit the undisputed facts of the case. As I agree with Defendant that this opinion is an impermissible legal conclusion, I will address only this issue.

District courts "must ensure that an expert does not testify as to the governing law of the case." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." Id. (citing First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981)). "[An] expert [is] not free to reach conclusions about the reasonableness of [a party's] [*131] beliefs when such an opinion necessarily would have required an interpretation of the relevant . . . law." In re Wellbutrin SR, Nos. 04-5525, 04-5898, 05-396, 2010 U.S. Dist. LEXIS 144273, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010); see also QVC, Inc. v. MJC Am., Ltd., No. 08-3830, 2012 U.S. Dist. LEXIS 468, 2012 WL 13565, at *2 (E.D. Pa. Jan. 4, 2012) (noting that experts may not apply the resulting law to the facts of a case to draw a legal conclusion).

I addressed a similar challenge in King Drug Co. of Florence Inc. v. Cephalon, Inc., Nos. 06-1797, 06-1833, 06-2768, 2015 U.S. Dist. LEXIS 150151, 2015 WL 6750899 (E.D. Pa. Nov. 5, 2015). In that antitrust case, the issues turned substantially on whether the litigation and settlement of a prior patent suit brought by two of the antitrust defendants was valid or whether that settlement was used to prevent later competition. 2015 U.S. Dist. LEXIS 150151, [WL] at *1. The defendants had sought to present expert testimony that various legal arguments they made during the patent infringement lawsuit were "reasonable" and that a reasonable litigant in the defendants' position could have realistically expected success on the merits. 2015 U.S. Dist. LEXIS 150151, [WL] at *15-16. In the face of a Daubert challenge by the plaintiff, the defendants contended that the experts were not presenting a legal opinion, but rather simply opining as to the customs and practices of the industry and the objective reasonableness of the parties' patent positions. 2015 U.S. Dist. LEXIS 150151, [WL] at *17. The defendants further argued that the experts provided valuable insights for the jury on the factors considered [*132] by drug manufacturers when contemplating infringement settlements. Id.

I disagreed with the defendants and found that a key issue in the case was whether the prior patent litigation was objectively baseless, such that no reasonable litigant could realistically expect success on the merits, and that the baseless lawsuit furthered anticompetitive activity. 2015 U.S. Dist. LEXIS 150151, [WL] at *17. The proposed experts were attorneys evaluating the merits of a legal argument by applying facts to the law. Id. As such, I determined that the expert's reasonableness opinions would "usurp the role of the jury and merely tell them which conclusion to reach as to an essential element." 2015 U.S. Dist. LEXIS 150151, [WL] at *17-18.

Similarly, in In re Wellbutrin SR Antitrust Litig., *supra*, the plaintiff sought to introduce expert opinions in an antitrust case also involving a sham litigation claim. 2010 U.S. Dist. LEXIS 144273, [WL] at *2. The experts were attorneys who opined that the defendant could not have had a reasonable expectation of success in the litigation. Id. The court found that to the extent the experts would testify as to relevant background information, such as patent practice, patent application procedure, or other areas related to patent law that would be helpful for a trier of fact, the experts were admitted. 2010 U.S. Dist. LEXIS 144273, [WL] at *6. To the extent, however, that [*133] the experts testified as to governing legal standards and applied those standards to the relevant facts, the court deemed these opinions impermissible legal opinions. 2010 U.S. Dist. LEXIS 144273, [WL] at *7.

In response to those decisions, the DPPs rely on In re Flonase Antitrust Litig., 884 F. Supp. 2d 184, 200 (E.D. Pa. 2012). That case, like the one before me, involved alleged sham citizen petitions. Id. at 188. The defendant offered an expert opinion that the petitions were "appropriate" and had "regulatory merit." Id. at 195-96. Considering plaintiff's Daubert challenge, the court allowed the expert to "explain that the petitions were 'within the FDA's jurisdiction' of topics properly considered in the citizen petition process" or were "within the FDA's purview." Id. at 197. The court further noted that the expert's testimony on the merits of the Citizen Petitions in the context of FDA regulatory policy and practice was relevant and helpful to the trier of fact. Id. at 198. However, the court concluded that the expert could not opine on the scientific merits of the citizen petitions and could merely offer opinions from an FDA regulatory and policy perspective. Id. at 199-200.

I find that Ms. Jaskot's opinions are more akin to the opinions excluded in King Drug and Wellbutrin than the one admitted in Flonase. Ms. Jaskot's opinion is not that Defendant's [*134] Citizen Petition was outside the FDA's jurisdiction of topics or that it did not satisfy the FDA's rules for when such petitions may be filed. Rather, the opinion is that the Citizen Petition was "[f]actually and [i]legally [b]aseless." (Jaskot Rep. p. 24.) Ms. Jaskot posits

three reasons for her conclusion. First, as to Defendant's request that the FDA not approve ANDAs that did not include a targeted pediatric exposure education program, Ms. Jaskot asserts that the studies relied upon by Defendant were insufficient and that the authority cited by Defendant did not legally support its request. (*Id.* ¶¶ 123-24.) Second, as to Defendant's request that the FDA refrain from approving ANDAs that lack child-resistant unit-dose packaging, Ms. Jaskot opines that Defendant provided inadequate evidence to support this request. (*Id.* ¶¶ 125-26.) Third, as to Defendant's request that the FDA not approve any ANDA for buprenorphine/naloxone tablets until it determined whether Defendant's decision to discontinue the tablet was for safety reasons, Ms. Jaskot opines that the study relied upon by Defendant to pull its tablet from the market was inherently flawed and, therefore, Defendant did not have [*135] "a sound scientific basis to support the actions requested in the Petition." (*Id.* at ¶¶ 127-33.) Ms. Jaskot then concludes that "[Defendant]'s Petition was not supported by evidence. Based on my many years of experience in industry evaluating and responding to citizen petitions, it is my professional opinion that [Defendant] did not have sound scientific basis for each of the requests stated in the Petition, that the Petition was factually and legally baseless, and no reasonable petitioner could expect the Petition to be granted." (*Id.* ¶ 133.)

Although Ms. Jaskot attempts to couch each of her statements in terms of whether the Citizen Petition conformed to the regulations governing the filing of citizen petitions, her opinion is, at its core, a pure legal conclusion as to whether the Citizen Petition had merit. This is not permissible. As one of the key issues in this case is whether Defendant's Citizen Petition was factually and legally baseless and used entirely for anticompetitive purposes, I find that Ms. Jaskot's opinion is a legal opinion that usurps the jury's role in applying the law to the facts.

VI. DEFENDANT'S MOTION TO EXCLUDE PLAINTIFFS' EXPERT OPINIONS ASSERTING OR RELYING [*136] UPON ASSERTIONS THAT ALLEGED RECKITT SAFETY MESSAGES WERE "FALSE," "MISLEADING," "DISPARAGING," "FABRICATED," "FRAUDULENT," "SHAM," OR "DECEPTIVE"

Defendant also seeks to preclude any of Plaintiffs' experts from relying on the assumption that Defendant's alleged safety claims were false, misleading, disparaging, fabricated, fraudulent, sham, or deceptive, including: (1) the DPPs' economist experts' assumption that Defendant's safety claims were false in order to prove that Defendant's alleged conduct was anticompetitive and resulted in measurable damages; and (2) Plaintiffs' experts' assumption that the allegedly false safety claims influenced the markets.

Proper consideration of this motion requires a more fulsome discussion of both the background of this issue and Defendant's argument. As set forth above, Plaintiffs contend that as part of Defendant's overall efforts to keep generic buprenorphine/naloxone tablets off the market and switch the market demand from tablets to branded film, Defendant developed a "safety story." According to Plaintiffs, Defendant repeatedly and without evidence claimed—both in marketing and promotion and in a Citizen Petition to the FDA—that tablets were [*137] more prone than film to a risk of pediatric exposure and to misuse, abuse, and diversion. Plaintiffs' theory posits that via this safety story, Defendant attempted to sway physicians into prescribing only film and to impede FDA approval of generic tablets.

According to Defendant, however, the veracity of its "safety" claims are backed by substantial unrefuted evidence. In its current Motion, Defendant asserts that none of Plaintiffs' expert opinions—aside from Professor Zettler's inadmissible legal opinion—affirmatively state that film does not offer safety advantages relative to tablets. Absent such evidence, Defendant asserts that none of Plaintiffs' experts can assume the falsity of Defendant's alleged promotional statements regarding damages or impact on the market. Ultimately, Defendant seeks to preclude all of Plaintiffs' experts from characterizing Defendant's alleged marketing claims (including claims relating to safety, pediatric exposure, abuse, diversion, or misuse) as "false," "misleading," "disparaging," "fabricated," "fraudulent," "unfounded," "sham," "baseless," "deceptive," or the like, and to strike any expert testimony that relies on such assumptions.

Defendant relies [*138] on five core assumptions: (a) Plaintiffs bear the burden of affirmatively proving the falsity of Defendant's safety statements about Suboxone products; (b) no Plaintiff expert testifies or is qualified to testify that the statements were actually false; (c) Plaintiffs' expert Patricia Zettler cannot testify that the statements were "false" under FDA standards; (d) falsity cannot be proven through lay testimony or evidence; and (e) therefore, no

expert may rely on the presumed falsity of Defendant's safety statements when rendering an opinion. I address each of these assumptions individually.

A. Whether Plaintiffs Must Affirmatively Prove that the Safety Statements Were Untrue

Defendant's first assumption turns on the definition of "false and misleading." In refuting Plaintiff's claims of false, disparaging, or fabricated safety claims, Defendant relies on a dictionary definition of "false" and "misleading" and contends that Plaintiffs must affirmatively prove that the safety statements at issue were untrue. Because Defendant argues that Plaintiffs have failed to meet this burden, Defendant presses that Plaintiffs' expert economists may not rely on such statements to prove antitrust impact [*139] or damages.

It is well established, however, that "[a]ntitrust analysis must always be attuned to the particular structure and circumstance of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation." Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411, 124 S. Ct. 872, 157 L. Ed. 2d 823 (2004). Therefore, I must look to the FDA's marketing rules to determine whether Defendant's safety statements were indeed "false" or "misleading."

The FDA defines "marketing" as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc., 499 F.3d 239, 243 (3d Cir. 2007) (citing 21 C.F.R. § 202.1(l)(1)), vacated on other grounds, 556 U.S. 1101, 129 S. Ct. 1578, 173 L. Ed. 2d 672 (2009). "Although advertising may also serve as a mechanism to distribute safety information about a drug, its primary purpose—unlike labeling is not to promote safety but rather to promote market expansion." Id.

Under the relevant regulations

An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

...

(ii) Contains a drug comparison that represents or suggests [*140] that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

...

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

...

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

21 C.F.R. § 202.1(e)(6).

Thus, the standard for whether the statements at issue here are "false, lacking in fair balance, or otherwise misleading" does not turn, as Defendant urges, on whether the statements are untrue, but rather on whether Defendant had substantial evidence or substantial clinical experience to support those statements. "Substantial evidence" is defined as "adequate and well-controlled [*141] investigations, including clinical investigations . . . by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses." 21 C.F.R. § 202.1(e)(4)(ii)(b). "Substantial clinical experience" means "substantial clinical experience adequately documented in medical literature or by other data . . . on the basis of which it can be fairly

and responsibly be concluded by qualified experts that the drug is safe and effective for such uses." *Id.* at § 202.1(e)(4)(ii)(c). Indeed, FDA officials have explained:

Promotional labeling or advertising is considered false or misleading if it contains claims that are not supported by substantial evidence. This includes, for example, claims about product uses (indications), dosing, and advantages over other products or interventions. Thus, comparative claims of effectiveness or safety in promotional labeling and advertising generally must be supported by substantial evidence from adequate and well-controlled trials that demonstrate that the drug will have the claimed effect (for example, superiority over another treatment). [*142]

To be considered "substantial evidence" of effectiveness, the trials would generally have to been designed to provide a fair and valid head-to-head comparison of the treatments in question (for example, the doses of compared products and treatment duration should be clinically comparable)

(Pls.' Resp. to Def.'s Safety Mot., Ex. 23, Joseph P. Griffin, et al., "Regulatory Requirements of the Food and Drug Administration Would Preclude Product Claims based on Observational Research," 31 *Health Affairs* 2188, 2190 (2012).)

Defendant attempts to avoid these regulations by positing two arguments. First, it contends the FDA advertising regulations have little bearing on the issue here because violations of the FDCA or its related regulations, even if proven, "do nothing to illuminate whether an antitrust violation occurred." (Def.'s Mot. to Preclude Expert Reliance on Allegedly False Safety Messages ("Def.'s Safety Mot.") 12.) Citing to the Third Circuit's decision in *Philadelphia Taxi Assoc., Inc. v. Uber Techs., Inc.*, 886 F.3d 332 (3d Cir.), cert denied, 139 S. Ct. 211, 202 L. Ed. 2d 126 (2018), Defendant contends that even if a defendant was "able to cut costs by allegedly violating . . . regulations, [the plaintiffs] cannot use the antitrust law to hold [the defendant] liable for these violations [*143] absent proof of anticompetitive conduct." *Id.* at 340.

Defendant's citation, however, avoids the very next portion of the sentence in *Philadelphia Taxi*, which states that "[e]ven unlawful conduct is 'of no concern to the antitrust laws' *unless it produces an anticompetitive effect.*" *Id.* (quotations omitted) (emphasis added); see also *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 U.S. Dist. LEXIS 177541, 2015 WL 958927, at *16 (D.N.J. Oct. 29, 2015) (allowing antitrust plaintiff to prove violation of FDA regulations as part of an overall anticompetitive scheme). As I noted previously, "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable." *In re Suboxone Antitrust Litig.*, 13-2445, 2017 U.S. Dist. LEXIS 627, 2017 WL 36371, at *8 (E.D. Pa. Jan. 4, 2018) (citing cases); see also *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.").

The allegation here is multi-layered: Defendant's repeated and willful violations of FDA advertising regulations in the form of unsubstantiated or "false" warnings about the comparative safety benefits between film and tablets—combined [*144] with the increase in the price of tablets and decrease in the price of film, the introduction of Suboxone film onto the market, the removal of Suboxone tablets from the market several months prior to generic approval, delay in the shared REMS, and an improper citizen petition—all contributed to a pattern of anticompetitive conduct resulting in an anticompetitive effect. To that end, Plaintiffs need not affirmatively prove that Defendant's marketing statements were "false" or "misleading" in the sense of being untrue. Rather, they need only prove that, at the time those statements were made, Defendant did not have substantial evidence or statistically significant data from head-to-head clinical trials.

Defendant's second effort to avoid the regulatory definition given to the terms "false" and "misleading" cites the Merriam-Webster Dictionary definition of "false" and "misleading" and asserts that these terms—as well as the terms "fabricated," "fraudulent," "sham," or "deceptive"—have well-understood colloquial meanings that signify dishonesty and deception and suggest that Defendant's safety claims were wrong. Defendant posits that a juror will not fully understand in the context of [*145] the case that the words "false" or "misleading," as used by

Plaintiffs' experts, simply mean that "at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials."

Defendant's concerns are nothing more than a fear that the jurors will not comprehend its theory of the case. To the extent that a witness testifies that certain marketing statements were false, misleading, or otherwise deceptive, counsel may use opening statements, closing statements, direct examination, or cross-examination to clarify the meaning of those terms. If a witness suggests that the marketing statements had the colloquial definition of false, counsel may use cross-examination to underscore that the witness has no such actual knowledge. Finally, Defendant will be free to request appropriate jury instructions on this issue. The mere possibility of confusion does not constitute grounds for disregarding the clear statutory and regulatory meaning of "false and misleading."

In short, to establish that Defendant's marketing and promotional statements comparing the safety of film and tablets were deceptive—as part of Defendant's overall anticompetitive scheme [*146] to prevent the intrusion of generic tablets on the market—Plaintiffs need only prove that the promotional statements were "false and misleading" as defined by the FDA. Under the FDA regulations, Defendant was not permitted to make statements about or offer comparisons between its drug and other drugs unless it had, at the time the statements were made, substantial evidence or substantial clinical experience to support those statements. To the extent Defendant did not have such evidence at the time it made those statements, Plaintiffs may properly rely on Defendant's actions—as part of an overall antitrust scheme—to establish an anticompetitive effect.

B. Whether Plaintiffs Have Expert Testimony to Support Their Claim that the Statements Were "False and Misleading"

Defendant's second assumption asserts that none of Plaintiffs' experts can opine that film does not offer safety advantages relative to tablets. Defendant reasons that only two of Plaintiffs' experts—Drs. Westreich and Jewell—claim to possess expertise allowing them to analyze the scientific and epidemiological evidence relating to the safety of Suboxone film and Suboxone tablets. Both witnesses, however, clearly acknowledge [*147] that they will not express an opinion as to whether or not film would pose fewer safety risks to public health as compared to Suboxone tablets and that they did not make affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric. (Westreich Dep. 189-90; Jewell Dep. 22-25.) Rather, these witnesses conclude that there is simply not enough evidence to determine one way or another whether film offers diminished susceptibility to risks of pediatric exposure, or use, misuse and diversion. According to Defendant, such testimony is insufficient to establish that Defendant's statements were "false" or "misleading."

Plaintiffs, however, do not purport to offer an expert to directly rebut Defendant's statements that film poses fewer safety risks than tablets. Rather, Plaintiffs' experts seek to testify that Defendant's safety claims were not grounded in fact and science and were not supported by substantial evidence or substantial clinical studies. To that end, Plaintiffs proffer the testimony of Nicholas Jewell who (a) considers, from a statistical perspective, the data, analysis, and conclusions regarding the comparative safety [*148] of the film formulation of Suboxone versus the tablet formulation of Suboxone as set forth in two articles upon which Defendant relied, RADARS I and RADARS II; and (b) comments on the reliability, from a statistical perspective, of certain analyses purporting to compare the persistency and relapse rates of patients taking the formulation of Suboxone or the tablet formulation. (Jewell Rep. ¶ 9.) Based on multiple factors detailed throughout his report, Dr. Jewell opines that the conclusions set forth in the RADARS I and RADARS II articles were not reliable and, therefore, any claims by Defendant that tablets were less safe than film were "without substance statistically." (*Id.* ¶¶ 10-15.)

Plaintiffs also offer Dr. Laurence Westreich who connects the "false and misleading" statements to the alleged anticompetitive impact. Dr. Westreich opines that "[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical associations, and interacting with other doctors," he, as the "average, reasonable" physician, would be impacted and influenced by Reckitt's claims about the tablets' dangers, would have maintained an anti-tablet bias after generic [*149] tablets became available, and would have factored information about impending tablet withdrawal into treatment decisions. (Westreich Rep. ¶¶ 235-70.) In addition, Dr. Westreich offers an assessment, based on his experience in peer review, of whether the circumstances under

which certain or Reckitt's studies were prepared violated well-established safeguards on independent, accurate, and reliable studies. (See, e.g., Westreich Rep. ¶ 103 ("Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry."); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 ("From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis."); ¶ 155 ("documents extrinsic to the paper also show that it was finalized under extraordinary time pressures, which may also have contributed to data inaccuracies."); ¶ 189 ("as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse [*150] and Diversion study.")) None of these statements/opinions speak to false safety claims.

In short, neither Dr. Jewell nor Dr. Westreich opines, from a scientific standpoint, that Defendant's safety claims were wrong. They need not do so under FDA standards. Rather, these experts provide an opinion that the underlying studies on which Defendant based its statements did not constitute "substantial evidence"—*i.e.*, they were not "adequate and well-controlled investigations, including clinical investigations . . . by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses." [21 C.F.R. § 202.1\(e\)\(4\)\(ii\)\(b\)](#). In turn, I find that the opinions of these experts provide an adequate foundation for the assertion that Defendant's safety messages were false and misleading.

C. Whether Professor Zettler May Opine that Defendant's Statements Were "False" or "Misleading"

Plaintiffs also offer Professor Patricia Zettler who opines in part that (a) Reckitt's promotion of the Suboxone film as less prone to misuse, diversion, and pediatric exposure [*151] than the Suboxone tablet was false or misleading in violation of the FDCA and FDA's regulations because the claims were not supported by statistically significant data at the time; and (b) if she were an attorney counseling a drug sponsor client in the position of Reckitt, she would have advised her client not to make such safety claims. Specifically, she states:

Reckitt's promotion of the Suboxone Film product as less prone to misuse, diversion, and pediatric exposures than the Suboxone Tablet product was false or misleading in violation of the FDCA and FDA's regulations, and inconsistent with FDA policies, because, at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials adequately designed to compare the two products or equivalently robust data.

(Zettler Rep. ¶ 19(c).)

Defendant posits four challenges to Professor Zettler's opinion. First, it again challenges her qualifications. Second, it asserts that her opinions constitute improper legal conclusions. Third, it argues that her legal opinions are irrelevant to antitrust liability. Finally, it claims that Professor Zettler's legal opinion rests on a botched legal [*152] analysis.

1. Qualification

Defendant first alleges that Professor Zettler is not qualified to assess whether any safety claim is either proven or substantiated, as she is a lawyer without a professional background in epidemiology, statistics, or medicine. Professor Zettler, however, makes no attempt to look at scientific evidence or scientifically study whether film has any safety benefits as opposed to tablet products. Accordingly, I need not address her qualifications from that perspective. As set forth in detail *supra*, I find Professor Zettler qualified under Daubert to render the opinions set forth in her report.

2. Improper Legal Conclusion

Defendant next argues that Professor Zettler's opinion that alleged safety claims did not comply with the FDCA and FDA regulations is an improper legal conclusion. Defendant urges that because Professor Zettler explores the legal

question of whether Defendant's marketing claims applied to her interpretation of the governing regulations and statutes, it is pure exercise in statutory interpretation and not appropriate for expert review.

As explained in detail above, expert witnesses are prohibited from rendering a legal opinion because "it would usurp [*153] the District Court's pivotal role in explaining the law to the jury." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Nonetheless, "expert testimony that implicates or touches on legal issues is not per se inadmissible." Comcast Cable Communs., LLC v. Sprint Communs. Co., LP, 203 F. Supp. 3d 499, 546 (E.D. Pa. 2016). "Courts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper." In re Wellbutrin SR Antitrust Litig., Nos. 04-5525, 04-5898, 05-396, 2010 U.S. Dist. LEXIS 144273, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010) (citing cases). As observed by the court in In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009):

A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury. An expert may offer testimony embracing an ultimate issue of fact that the jury will decide. Fed. R. Evid. 704(a). Cross-examination and competing expert testimony by Merck's regulatory experts will ensure that the jury carefully weighs her testimony.

Id. at 190-91.

Numerous courts have found that "the testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is [*154] helpful to a jury." In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 478-79 (S.D.N.Y. 2016) (citing Wells v. Allergan, Inc., No. 12-973, 2013 U.S. Dist. LEXIS 185373, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) (finding expert testimony about FDA regulations would not "usurp" the role of the trial judge); In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 09-2100, 2011 U.S. Dist. LEXIS 145593, 2011 WL 6302287, at *25 (S.D. Ill. Dec. 16, 2011) (discussing FDA regulations and finding that "[t]o the extent [the expert] does offer legal conclusions, the Court finds that [the expert's] testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. [The expert's] testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not [the expert] nor any other witness, will instruct the jury on the law in this case."); In re Fosamax, 645 F. Supp. 2d at 191 (denying motion to preclude expert from "testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith"). In particular, courts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA. See, e.g., Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 659-60 (E.D. Pa. 2012) (experts permitted to testify that defendants withheld information from FDA and failed to conduct a proper safety analysis); Bartoli v. Novartis Pharms. Corp., No. 13-724, 2014 U.S. Dist. LEXIS 52956, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (finding that expert could opine on the reasonableness of defendant's conduct [*155] in its interactions with the FDA and compliance with FDA regulations, including defendant's interactions with FDA with respect to labels and warnings); Pfizer v. Teva Pharms. USA, Inc., 461 F. Supp. 2d 271, 278-79 (D.N.J. 2006) (finding admissible expert testimony regarding FDA regulation of labeling, advertising, and promotion of prescription drugs, and to what extent the pharmaceutical company complied with those requirements).

Here, the key issue in this case is not whether Defendant violated FDA regulations regarding its marketing of film and its safety statements regarding tablets.¹⁸ Rather, it is whether Defendant made unsupported safety claims

¹⁸ Defendant cites to several cases for the proposition that the meaning of federal regulations is not a question of fact on which experts may opine, but rather a question of law to be resolved by the court. These cases are distinguishable. In Bammerline v. Navistar International Transportation Corp., 30 F.3d 898 (7th Cir. 1994), for example, a driver brought an action against a truck manufacturer for injuries sustained in an accident, alleging that the manufacturer designed the seat belt assembly improperly. Id. at 900. Given that the ultimate issue in the case involved whether the seat belt assembly was defective, the court found that an

regarding Suboxone tablets in an effort to divert the market away from tablet prescriptions and further its alleged anticompetitive scheme. To that end, Professor Zettler engages in an extensive discussion of the regulations regarding advertising and promotion in the prescription drug industry. Specifically, she states:

- Under FDA regulations, a drug sponsor generally cannot make claims regarding the safety and effectiveness of its drug product unless and until those claims are supported by sound scientific evidence at the time they are made, regardless of whether such claims are made in writing or orally. (Id. [*156] ¶ 51.)
- The requirement to comply with FDA marketing regulations and policies is well known in the pharmaceutical industry. Promotional materials provided to healthcare professionals on behalf of a company should make claims about a product only when substantiated (Id. ¶ 144.)
- Defendant understood that FDA and FDCA promotional materials had to have statistically significant data supporting the claims made therein in order to avoid being "false, lacking in fair balance, or otherwise misleading." (Id. ¶¶ 145-51.)
- From 2009 to August 2010, Defendant actively promoted Suboxone Film as safer than Suboxone tablets because it had lower risks of abuse, diversion, and misuse and because it had a lower risk of unintended pediatric exposure. (Id. ¶¶ 152-54.)
- At the time Defendant was issuing those statements, there was insufficient data to support the accuracy of claims that the Film product was less prone to misuse, diversion, and pediatric exposures than the tablet product was. FDA officials on multiple occasions concluded that the existing evidence did not support those assertions, and Defendant's own documents and testimony show that the company was not aware of sufficient scientific evidence [*157] to support its claims that Film was safer than tablets. (Id. ¶¶ 155-60.)

Such testimony may assist a jury not only in understanding the federal regulations and what they require, but also how Defendant's own testimony and admissions reveals that its communications did not comply with FDA and FDCA standards for prescription drug promotional materials.

However, the next two paragraphs of Professor Zettler's report cross the line into an inadmissible legal opinion when she reaches her final conclusions that: (1) Defendant's claims that film was less prone to misuse, diversion, and pediatric exposures than tablets were false or misleading under the FDCA and FDA regulations, in that the claims were not substantiated by sufficient scientific evidence at the time they were made, and (2) had Defendant been her client, she would have advised it that it should not make claims that film was safer than tablets because such claims would violate FDA requirements in the absence of head-to-head clinical trials adequately designed to compare the products or equivalently robust scientific evidence. (Id. ¶¶ 161-62.) Such conclusions are for the jury to reach upon application of the law to the facts. [*158] Therefore, to the extent Professor Zettler seeks to offer these ultimate opinions, her testimony will be excluded.

3. Relevance

Defendant's third challenge to Professor Zettler's opinion contends that her opinions are irrelevant. It posits that Plaintiffs cannot bring a private cause of action under the FDCA, and that violations of the FDCA or its regulations, even if proven, do nothing to illuminate whether an antitrust violation has occurred. Thus, Defendant concludes that testimony about alleged FDCA violations tells us nothing about whether such conduct had an anticompetitive effect.

expert's testimony that the seat belt assembly did not comply with Federal Motor Vehicle Safety Standards impermissibly usurped the role of the jury. Id. Similarly, [*Gordon v. New England Central Railroad, Inc.*, No. 17-154, 2019 U.S. Dist. LEXIS 146169, 2019 WL 4068639 \(D. Vt. Aug. 28, 2019\)](#) involved a negligence claim against a railroad for failure to appropriately maintain track facilities. The court found that an expert report which was to "determine the standard of care" under federal regulations was an improper legal conclusion because "standard of care" is a legal decision within the province of the court. [*2019 U.S. Dist. LEXIS 146169, \[WL\] at *3*](#). It further found that expert's opinion that the violation of federal regulations caused the collapse of the embankment was an ultimate conclusion exclusively within the province of the jury. Id.

This argument represents yet another attempt by Defendant to sever Plaintiffs' theory into several individual causes of action. As I have previously noted, false or misleading disparagement of another company's product "can give rise to antitrust liability, especially when it is combined with other anticompetitive acts." *In re Suboxone Antitrust Liab.*, 64 F. Supp. 3d 665, 682 (3d Cir. 2014) (quotations and citations omitted). I further remarked that "[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film." *Id.*; see also *Int'l Travel Arrangers, Inc. v. Western Airlines, Inc.*, 623 F.2d 1255, 1268 (8th Cir. 1980) (holding that alleged [*159] monopolist's false, misleading, and deceptive advertising against another company for the purpose of preventing any effective competition was an unreasonable restraint of trade). Thus, although Plaintiffs cannot use antitrust law to hold Defendant liable for stand-alone violations of administrative regulations or unlawful conduct, those violations are relevant to Plaintiffs' proof of an overarching scheme that had an anticompetitive effect. I decline to exclude Professor Zettler's report on this ground.

4. Reliability

Defendant's final challenge to Professor Zettler's analysis contends that it rests upon a "botched legal analysis." (Def.'s Safety Mot. 13.) In support of this position, Defendant sets forth three arguments.

First, Defendant contends that Professor Zettler's analysis is untethered to the text of the FDCA because she relies on a provision of the FDCA that a drug is misbranded if "[i]ts labeling is false or misleading." 21 U.S.C. § 352(a). But, according to Defendant, the definition of "labeling" is limited to "written, printed, and graphic material," 21 U.S.C. § 321(m), and almost all of the alleged communications Professor Zettler deems "false and misleading" are oral discussions or internal memorandum.

Professor [*160] Zettler's opinion, however, is not limited to "labeling," but rather focuses on "prescription drug advertising and promotion." (Zettler Rep. ¶ 145.) As noted above, the FDA defines marketing as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. *Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc.*, 499 F.3d 239, 243 (3d Cir. 2007) (emphasis added) (citing 21 C.F.R. § 202.1(l)(1)); see also *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 U.S. Dist. LEXIS 58900, 2009 WL 2043604, at *2 (D.N.J. July 10, 2009) ("In addition to regulating the labeling of prescription drugs, the FDA is also empowered under the FDCA to regulate prescription drug advertising and marketing, including marketing directed at physicians and the medical community at large.") (emphasis added); *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163, 168 (D.N.H. 2007) (noting that the FDA is "authorized to take enforcement action against companies that use false and misleading advertising materials. . . . This regulatory authority also extends to oral misrepresentations by sales representatives."). Thus, I find no merit to Defendant's first argument.

Second, Defendant contends that courts construing the FDCA's misbranding provisions in light of the protections of the *First Amendment* have held that an accusation of misbranding [*161] cannot be established absent proof that a claim was untrue. The cases cited by Defendant in support of this proposition are distinguishable, as they involve criminal prosecution of a drug company for violations of the branding regulations. See *United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) (finding that FDCA's misbranding provisions do not criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives "because such a construction—and a conviction obtained under the government's application of the FDCA—would run afoul of the *First Amendment*"); *Amarin Pharma, Inc. v. United States FDA*, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (holding that under Caronia, the FDA may not bring a misbranding action against a manufacturer based on truthful promotional speech alone). This case, by contrast, is not a misbranding action brought by a governmental entity, but rather an antitrust action alleging that Defendant's "false and misleading" promotion—as defined by the applicable regulations—was part of a broader antitrust scheme to preclude generic competition. Defendant offers no authority for the proposition that such an action is violative of the *First Amendment*.

Finally, Defendant contends that Professor Zettler relies on a regulation relating to "advertisement[s] for a prescription drug," which [*162] states that comparative claims should be demonstrated "by substantial evidence or substantial clinical experience." According to Defendant, however, Professor Zettler does not analyze any advertisements. Moreover, Defendant asserts that no authority requires head-to-head clinical trials in the promotional advertising sphere, and that FDA guidance provides that promotional claims are subject only to the lesser "competent and reliable information" standard.

These arguments are not a basis for exclusion of Professor Zettler's testimony—indeed, they highlight its necessity. FDA regulations and their application are confusing, such that a jury cannot be expected to understand them without expert assistance. Flaws in Professor Zettler's discussion of FDA regulatory standards are easily and more appropriately addressed on cross-examination or through Defendant's own rebuttal experts.

5. Conclusion as to Professor Zettler

In sum, although Professor Zettler cannot offer an opinion as to whether Defendant's promotional statements were "false and misleading," she may provide expert testimony regarding the requisite standards under the regulations. Additionally, she may discuss, based on her review [*163] of relevant documents, what type of support Defendant had for its safety claims.

D. Whether Falsity May Be Proven Through Lay Testimony or Evidence

Defendant's next assumption rests on the notion that Plaintiffs cannot "use non-expert testimony provide a foundation for their experts' assumptions on the supposed falsity of Reckitt's alleged safety claims." (Def.'s Safety Mot. 17.) Defendant goes on to cite numerous cases for the proposition that courts have required expert testimony in pharmaceutical product liability cases on issues of causation. They assert that comparative pharmaceutical safety—such as comparisons between Suboxone tablet and Suboxone film—is beyond the experience and understanding of lay jurors. Yet, according to Defendant, Plaintiffs have no expert testimony to this issue. Moreover, Defendant challenges Plaintiffs' reliance on an FDA "General Advice letter" from 2010 stating that the FDA did not agree that Reckitt had proven that film's packaging "provides meaningful incremental protection against pediatric exposure." (Def.'s Safety Mot., Ex. 47.)

Defendant's analysis is flawed for two reasons. First, and as repeatedly set forth above, in order to establish that Defendant's [*164] safety claims were false and misleading, Plaintiffs need not affirmatively prove that tablets were as safe or safer than film. Rather, under the FDA regulations, they need only establish that Defendant lacked a reliable scientific basis on which to make their safety claims. To that end, Plaintiffs have proffered expert witness testimony from Professor Jewell and Dr. Westreich, both of whom opine as to the reliability of the studies on which Defendant based its safety claims. Moreover, Plaintiffs offer Professor Zettler to describe FDA marketing regulations and discuss what constitutes substantial evidence to support a comparative pharmaceutical claim. Plaintiffs need not offer any expert testimony to prove that film was not, in fact, safer than tablets.

Second, Plaintiffs have put forth documentary evidence that Defendant lacked a scientific basis for its claim, including (1) the FDA's June 2009 internal memorandum that Defendant's film NDA "[did] not provide evidence to compare the safety profile of the Suboxone strip to the Suboxone tablet"; (2) the FDA's 2010 letter stating that the FDA did not agree that Defendant had proven that film's packaging provided "meaningful incremental [*165] protection against pediatric exposure" because Defendant provided "no data" to support this claim;¹⁹ and (3) the FDA's August 2010 medical review stating that although Defendant "has implied that [Film] may represent an

¹⁹ Defendant asserts numerous challenges to this letter, arguing that (a) it does not state that the safety claims were false; (2) to the extent it can be read to state that film did not possess any safety benefits, "the letter would be expressing an inadmissible opinion with no foundation"; and (3) the passages relied upon by Plaintiffs are inadmissible hearsay. These arguments are not appropriate for resolution in this Daubert motion.

advantage over the current tablet products with respect to diversion . . . there is no basis for comparison, [and] there does not appear to be any reason to conclude that this formulation rendered the study drug particularly resistant to diversion." (Pls.' Resp. to Safety Mot., Ex. 4 P 144; Ex. 1 P 96; Ex. 12 P 156.) To the extent Defendant can rebut this evidence at trial, it is free to do so, and the jury can choose which story to credit.

Simply put, such "non-expert" evidence provides a foundation on which Plaintiffs can claim that, under the FDA regulations, Defendant's safety claims were "false and misleading."

E. Whether Plaintiffs' Experts on Antitrust Impact and Damages May Rely on Assertions that Defendant's Safety Messages Were False or Misleading

As a culmination of its motion, Defendant contends that Plaintiffs' experts cannot rely on the unproven assumption that film safety claims are false. According to Defendant, Plaintiffs' causation and damages experts purport to rely on a conclusion that has not been substantiated [*166] by any Plaintiff expert: that film does not provide safety benefits with respect to pediatric exposure, abuse, or diversion. Arguing that it is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record,²⁰ Defendant requests that I preclude all of Plaintiffs' experts from characterizing Defendant's alleged marketing claims as "false," "misleading," "disparaging," "fabricated," "fraudulent," "unfounded," "sham," "deceptive," or the like, and strike all such testimony contained within the reports of Plaintiffs' experts Professor Zettler, Dr. Berndt, Dr. Conti, Dr. Emch, Ms. Jaskot, Dr. Lamb, Ms. Tso, and Dr. Verscharen.

Defendant's request, however, asks me to rule on an issue of fact, i.e., whether Defendant had substantial evidence to support its safety claims at the time they were made. Neither Daubert motions nor summary judgment motions are proper vehicles for such a request. Rather, "[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination." [Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 \(3d Cir. 2002\)](#). Thus, [*167] to the extent that Plaintiffs can prove at trial that Defendant's safety claims were "false and misleading" as defined in the FDA and FDCA regulations, Plaintiffs' causation and damages experts may analyze these claims, in conjunction with the remainder of Defendant's challenged conduct, to opine on the ultimate effect on the market and resulting damages.

VII. CONCLUSION

I will grant the Phase I Daubert Motions in part and deny them in part as detailed in this Opinion. An appropriate Order follows.

ORDER

AND NOW, this 24th day of November, 2020, upon consideration of (1) the Direct Purchaser Plaintiffs' Motion to Exclude Certain Opinions of Reckitt Experts Nicholas M. Fleischer and Sheldon T. Bradshaw (Civ. A. No. 13-2445, Doc. No. 623; Civ. A. No. 16-5073, Doc. No. 394) and Defendant's Response (Civ. A. No. 13-2445, Doc. No. 629; Civ. A. No. 16-5073, Doc. No. 399); (2) the State Plaintiffs' Motion to Exclude the Opinions of Dolores Curtis, Ph.D. (Civ. A. No. 16-5073, Doc. No. 392) and Defendant's Response (Civ. A. No. 13-2445, Doc. No. 628; Civ. A. No. 16-5073, Doc. No. 398); (3) Defendant's Omnibus Motion to Exclude Certain Opinions of Nicholas Jewell, Laurence

²⁰ Defendants cite two cases for this proposition, neither of which are applicable here. See [Meadows v. Anchor Longwall and Rebuild, 306 F. App'x 781, 790 \(3d Cir. 2009\)](#) (excluding expert where testimony did not fit with the otherwise uncontroverted evidence before the court); [Brugler v. Unum Grp., No. 15-1031, 2019 U.S. Dist. LEXIS 158503, 2019 WL 4452226, at *15 \(M.D. Pa. Sept. 17, 2019\)](#) (excluding expert testimony where it was based on mere assumptions without any factual founding, thus rendering testimony unreliable).

Westreich, Yvonne Tso, **[*168]** Robert Verscharen, Patricia Zettler, and Deborah Jaskot (Civ. A. No. 13-2445, Doc. No. 625; Civ. A. No. 16-5073, Doc. No. 396) and Plaintiffs' Response (Civ. A. No. 13-2445, Doc. No. 631; Civ. A. No. 16-5073, Doc. No. 401); and (4) Defendant's Motion to Exclude Plaintiffs' Expert Opinions Asserting or Relying Upon Assertions that Alleged Reckitt Safety Messages Were "False," "Misleading," "Disparaging," "Fabricated," "Fraudulent," "Sham," or "Deceptive" (Civ. A. No. 13-2445, Doc. No. 624; Civ. A. No. 16-5073, Doc. No. 395) and Plaintiffs' Response (Civ. A. No. 13-2445, Doc. No. 630; Civ. A. No. 16-5073, Doc. No. 400), it is hereby ORDERED that the Motions are GRANTED IN PART and DENIED IN PART as set forth in detail in the Court's accompanying Memorandum Opinion.

BY THE COURT:

/s/ Mitchell S. Goldberg

MITCHELL S. GOLDBERG, J.

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